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Proclamation 9208 of November 7, 2014

The President

Veterans Day, 2014

By the President of the United States of America

A Proclamation

Since the birth of our Nation, American patriots have stepped forward to serve our country and defend our way of life. With honor and distinction, generations of servicemen and women have taken up arms to win our independence, preserve our Union, and secure our freedom. From the Minute-men to our Post-9/11 Generation, these heroes have put their lives on the line so that we might live in a world that is safer, freer, and more just, and we owe them a profound debt of gratitude. On Veterans Day, we salute the Soldiers, Sailors, Airmen, Marines, and Coast Guardsmen who have rendered the highest service any American can offer, and we rededicate ourselves to fulfilling our commitment to all those who serve in our name.

Today, we are reminded of our solemn obligation: to serve our veterans as well as they have served us. As we continue our responsible drawdown from the war in Afghanistan and more members of our military return to civilian life, we must support their transition and make sure they have access to the resources and benefits they have earned. My Administration is working to end the tragedy of homelessness among our veterans, and we are committed to providing them with quality health care, access to education, and the tools they need to find a rewarding career. As a Nation, we must ensure that every veteran has the chance to share in the opportunity he or she has helped to defend. Those who have served in our Armed Forces have the experience, skills, and dedication necessary to achieve success as members of our civilian workforce, and it is critical that we harness their talent.

Across our country, veterans who fought to protect our democracy around the globe are strengthening it here at home. Once leaders in the Armed Forces, they are now pioneers of industry and pillars of their communities. Their character reflects our enduring American spirit, and in their example, we find inspiration and strength.

This day, and every day, we pay tribute to America's sons and daughters who have answered our country's call. We recognize the sacrifice of those who have been part of the finest fighting force the world has ever known and the loved ones who stand beside them. We will never forget the heroes who made the ultimate sacrifice and all those who have not yet returned home. As a grateful Nation, let us show our appreciation by honoring all our veterans and working to ensure the promise of America is within the reach of all who have protected it.

With respect for and in recognition of the contributions our service members have made to the cause of peace and freedom around the world, the Congress has provided (5 U.S.C. 6103(a)) that November 11 of each year shall be set aside as a legal public holiday to honor our Nation's veterans.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, do hereby proclaim November 11, 2014, as Veterans Day. I encourage all Americans to recognize the valor and sacrifice of our veterans through appropriate public ceremonies and private prayers. I call upon Federal, State, and local officials to display the flag of the United States and to participate in patriotic activities in their communities. I call on

all Americans, including civic and fraternal organizations, places of worship, schools, and communities to support this day with commemorative expressions and programs.

IN WITNESS WHEREOF, I have hereunto set my hand this seventh day of November, in the year of our Lord two thousand fourteen, and of the Independence of the United States of America the two hundred and thirty-ninth.

A handwritten signature in black ink, appearing to be "Barack Obama", with a large circular flourish and a horizontal line extending to the right.

Presidential Documents

Proclamation 9209 of November 7, 2014

World Freedom Day, 2014

By the President of the United States of America

A Proclamation

For nearly three decades, the Berlin Wall divided a nation and stood as one symbol of a system that denied individuals the freedoms that are the right of every person. It separated families and suppressed free will and self-determination—but while it tried to contain the yearnings of a courageous and unwavering people for liberty and justice, it could not crush them. Twenty-five years ago today, Germans from East and West came together to tear down the Wall and begin the work of building an open and prosperous society. On World Freedom Day, we honor a generation that refused to be defined by a wall, and we reaffirm our commitment to stand with all those who seek to join the free world.

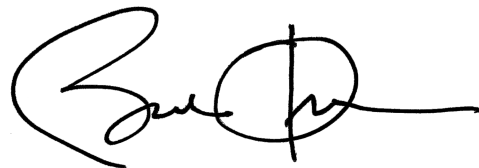
The images of this extraordinary event are seared in our memory and enshrined in our history: brave crowds climbing atop an old barrier and Berliners reuniting in city streets. But the victory of 1989 was not inevitable. We will not forget those who risked bullets, dug through tunnels, leapt from buildings, and crossed barbed wire, minefields, and a mighty river in pursuit of freedom. In their struggle—and in the memory of all those who did not live to see Berlin united and free—Americans see our own past, as well as the spirit of citizens around the world who long for opportunity and are willing to do the hard work of building a democracy.

America stood with those on both sides of the Iron Curtain who held fast to the belief that a better future was possible, and as the Berlin Wall fell, it spurred a more integrated, more prosperous, and more secure Europe. Today, Germany is one of our strongest allies. And as we pay tribute to our shared past, we are reminded that upholding peace and security is the responsibility of every nation. There is no progress without sacrifice and no freedom without solidarity, and we cannot shrink from our role of advancing the values in which we believe.

The story of Berlin shows us that with grit and determination, we have the power to shape our own destiny, even in the face of impossible odds. As we celebrate a triumph over tyranny, we also recognize that the challenges to peace and human dignity continue in our complex world and that complacency is not the character of great nations. Let us resolve to extend a hand to those who reach for freedom still and continue the pursuit of peace in our time.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim November 9, 2014, as World Freedom Day. I call upon the people of the United States to observe this day with appropriate ceremonies and activities, reaffirming our dedication to freedom and democracy.

IN WITNESS WHEREOF, I have hereunto set my hand this seventh day of November, in the year of our Lord two thousand fourteen, and of the Independence of the United States of America the two hundred and thirty-ninth.

A handwritten signature in black ink, appearing to be "Barack Obama", with a large circular flourish at the end.

Rules and Regulations

Federal Register

Vol. 79, No. 219

Thursday, November 13, 2014

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 27, 28, 29, 51, 52, 54, 56, 58, 62, 70, 75, and 91

[Document Number AMS-LPS-13-0050]

RIN 0581-AD36

Process for Establishing Rates Charged for AMS Services

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: The Agricultural Marketing Service (AMS) is amending its regulations to provide for a set of standardized formulas by which fees are calculated. The fees are calculated using formulas to account for all costs incurred by AMS in providing these services. Each year, fees will be announced in a notice in the **Federal Register** by June 1 and take effect at the start of the fiscal year, crop year, or as required by specific laws. This action provides greater transparency to the customers we serve as to how the fees are derived.

The standardized formulas will be used to calculate fees that AMS charges for providing voluntary grading, inspection, certification, auditing and laboratory services for a variety of agricultural commodities including meat and poultry, fruits and vegetables, eggs, dairy products, and cotton and tobacco. The fees will also apply to those persons requesting such services including producers, handlers, processors, importers and exporters. Fees charged for inspection of fruits, vegetables, and specialty crops subject to the Agricultural Marketing Agreement Act of 1937 are also affected by this rule.

Provisions of this rule do not supersede rates established by

Memoranda of Understanding, Marketing Orders, or by cooperative agreements already in place. Furthermore, the cotton program will continue to consult with its industry before rates are established.

DATES: *Effective Date:* This rule is effective December 15, 2014.

FOR FURTHER INFORMATION CONTACT: For further information contact, Sonia N. Jimenez, AMS, U.S. Department of Agriculture, Room 3069-S, 1400 Independence Ave. SW., Washington, DC 20250; telephone (202) 720-5115, fax (202) 720-8477.

SUPPLEMENTARY INFORMATION:

Background

The Agricultural Marketing Act of 1946, as amended, (AMA) (7 U.S.C. 1621-1627), provides for the collection of fees to cover costs of various inspection, grading, certification or auditing services covering many agricultural commodities and products. The AMA also provides for the recovery of costs incurred in providing laboratory services. The Cotton Statistics and Estimates Act (7 U.S.C. 471-476) and the U.S. Cotton Standards Act (7 U.S.C. 51-65) provide for classification of cotton and development of cotton standards materials necessary for cotton classification. The Cotton Futures Act (7 U.S.C. 15b) provides for futures certification services and the Tobacco Inspection Act (7 U.S.C. 511-511s) provides for tobacco inspection and grading. These Acts also provide for the recovery of costs associated with these services. This action sets formulas to calculate these fees and any other fee currently being charged under these statutes. The table below shows the program regulations and types of fees charged for AMS services.

Cotton Fees

Cotton Statistics and Estimates Act (7 U.S.C. 471-476)
U.S. Cotton Standards Act (7 U.S.C. 51-65)
Cotton Futures Act (7 U.S.C. 15b)
7 CFR Part 27—Cotton Classification Under Cotton Futures Legislation
Subpart A—Regulations; §§ 27.80-27.90; Costs of Classifications and Micronaire
7 CFR Part 28—Cotton Classing, Testing, and Standards
Subpart A—Regulations Under the United States Cotton Standards Act;

§§ 28.115-28.126; Fees and Costs
Subpart D—Cotton Classification and Market News Service for Producers; §§ 28.909; Costs
§§ 28.910; Classification of samples and issuance of classification data
§§ 28.911; Review classification

Dairy Fees

The Agricultural Marketing Act of 1946, as amended, (AMA) (7 U.S.C. 1621-1627)
7 CFR Part 58—Grading and Inspection, General Specifications for Approved Plants and Standards for Grades of Dairy Products
Subpart A—Regulations Governing the Inspection and Grading Services of Manufactured or Processed Dairy Products; §§ 58.38-58.46; Fees and Charges

Fruit and Vegetable Fees

The Agricultural Marketing Act of 1946, as amended, (AMA) (7 U.S.C. 1621-1627)
7 CFR Part 51—Fresh Fruits, Vegetables and Other Products (Inspection, Certification, and Standards)
Subpart A—Regulations; §§ 51.37-51.44; Schedule of Fees and Charges at Destination Markets
§§ 51.45; Schedule of Fees and Charges at Shipping Point Areas
7 CFR Part 52—Processed Fruits and Vegetables, Processed Products Thereof, and Other Processed Food Products
Subpart—Regulations Governing Inspection and Certification; §§ 52.41-52.51; Fees and Charges

Meat and Livestock Fees

The Agricultural Marketing Act of 1946, as amended, (AMA) (7 U.S.C. 1621-1627)
7 CFR Part 54—Meats, Prepared Meats, and Meat Products (Grading, Certification, and Standards)
Subpart A—Regulations; §§ 54.27-54.28; Charges for Service
7 CFR Part 54—Meats, Prepared Meats, and Meat Products (Grading, Certification, and Standards)
Subpart C—Regulations Governing the Certification of Sanitary Design and Fabrication of Equipment Used in the Slaughter, Processing and Packaging of Livestock and Poultry Products; §§ 54.1028; Charges for Service
7 CFR Part 62—Livestock, Meat and Other Agricultural Commodities

(Quality Systems Verification Programs)

Subpart A—Quality Systems

Verification Definitions §§ 62.300;

Fees and Other Costs for Service

7 CFR Part 75—Regulations for Inspection and Certification of Quality of Agricultural and Vegetable Seeds §§ 75.41; General

Poultry Fees

The Agricultural Marketing Act of 1946, as amended, (AMA) (7 U.S.C. 1621–1627)

7 CFR Part 56—Voluntary Grading of Shell Eggs

Subpart A—Grading of Shell Eggs;

§§ 56.45–56.54; Fees and Charges

7 CFR Part 70—Voluntary Grading of Poultry and Rabbit Products

Subpart A—Grading of Poultry and

Rabbit Products; §§ 70.70–70.78;

Fees and Charges

Science and Technology Fees

The Agricultural Marketing Act of 1946, as amended, (AMA) (7 U.S.C. 1621–1627)

7 CFR Part 91—Services and General Information (Science and Technology)

Subpart I—Fees and Charges;

§§ 91.37–91.45

Tobacco Fees

Tobacco Inspection Act (7 U.S.C. 511–511s)

7 CFR Part 29—Tobacco Inspection Subpart B—Regulations; §§ 29.123–29.129; Fees and Charges

Subpart F—Policy Statement and Regulations Governing the Identification and Certification of Non-quota Tobacco Produced and Marketed in Quota Area; §§ 29.9251; Fees and Charges

Grading, inspection and verification programs facilitate the movement of agricultural products through marketing channels—from growers to wholesalers, retailers and consumers—in a quick, efficient, and equitable manner. These services include the grading, inspection, or certification of quality factors in accordance with established U.S. Grade Standards; audits or accreditation according to International Organization for Standardization (ISO) standards and/or Hazard Analysis and Critical Control Point (HACCP) principles; and other marketing claims. The quality grades serve as a basis to reflect the value of agricultural commodities to both producers and consumers. AMS' grading and quality verification and certification, audit and accreditation, plant process and equipment verification, and laboratory approval services are voluntary tools paid for by

the users on a fee-for-service basis. The agriculture industry can use these tools to promote and communicate the quality of agricultural commodities to consumers. Laboratory services are provided for analytic testing, including but not limited to chemical, microbiological, biomolecular, and physical analyses.

Approximately 70 percent of AMS' operational budget is derived from fees assessed for services provided to agricultural industries. Changes in fee-for-service rates may result from fluctuating customer needs, increases in employee salary and benefit expenses, inflationary impact on non-labor operating expenses and fixed costs, and/or uncollected revenue (bad debt). Prior to this action, each AMS program individually proposed a fee change when a revenue shortfall was anticipated for a specific program or activity. As a result, these changes did not appear in a single unified fee schedule. Lack of certainty as to when annual fees would be announced may affect fiscal planning for the users of the services, especially if fees are changed in the middle of a contract or harvest season. In addition, because of the separate and repetitive use of the agency rulemaking process, programs experienced delays in recovering the full cost of the services they provided.

As a result, a number of AMS programs amended their regulations to provide for multi-year annual fee changes that were established by a single rulemaking action. While this enabled the Agency to collect revenue based on a revised fee each year, estimates used to set the projected annual rates did not always result in the Agency collecting revenues sufficient to cover its costs. Instead, in some instances, the Agency recovered partial costs.

In order to provide both transparency and predictability to the industries served and to allow the Agency to effectively plan for staffing, investments in infrastructure, and other resources, AMS is amending its regulations to provide for a set of standardized formulas by which fees are calculated. This process will use formulas established to determine fees for AMS's grading, inspection, certification, auditing, and laboratory services that cover expected costs while maintaining a reasonable reserve. AMS programs are required to sustain a certain minimum level of reserve funds in order to maintain fiscal responsibility should the program area undergo closure. Each program reserve level is affected by factors such as number of employees,

salaries, benefits, contracted obligations, and other items.

Currently, AMS performs financial analyses on an annual basis to determine whether the current fees are adequate to recover the costs incurred for providing these services. Historical or prior year cost and workload data, along with applicable projections are used to generate estimates of future obligations and revenues. This rule specifies that the rates be based on the actual cost and workload data of the previous fiscal year(s) or accounting period(s) (e.g. crop year) used by respective programs. On the basis of these analyses and using the formulas, AMS will determine the fees necessary to sustain program services. This increases predictability and provides information for planning purposes for the industries utilizing AMS user fee services.

The components (costs) that AMS will use to calculate the rates for services are the same costs used in calculating past rates.

As required by the Cotton Statistics and Estimates Act (7 U.S.C. 471–476), consultations regarding the establishment of the fee for cotton classification with U.S. cotton industry representatives will continue. Representatives of all segments of the cotton industry, including producers, ginner, bale storage facility operators, merchants, cooperatives, and textile manufacturers will continue to be addressed in various industry-sponsored forums.

Provisions of this rule will not supersede rates established by Memoranda of Understanding, Marketing Orders, cooperative agreements or other similar instruments. Under MOU, cooperative agreements, and similar instruments, fees are established based on specific agreements specified with an individual entity such as a State or university.

The outcome of this action is a transparent system for establishing fee rates for all AMS user fee programs, whereby financial and resource needs for continued operation are reviewed on a pre-determined cycle, using established formulas. This will avoid financial crises that may occur when reserve funds are rapidly depleted due to unanticipated business events, and will allow the Agency to more quickly adjust the cost of the services it provides. The information will also greatly benefit AMS customers by allowing them to better plan for the cost of AMS services.

Currently, AMS publishes a rule for each of the service fees it collects. This rulemaking action supports the

government's initiative to streamline processes and the Department's goal of formalizing processes to integrate openness, transparency, participation and collaboration.

Final Rule

With this action, AMS is amending its regulations in 7 CFR parts 27, 28, 29, 51, 52, 54, 56, 58, 62, 70, 75, and 91 by making public the formulas it uses to calculate user-fee rates. Making the standardized formulas a part of the regulations allows AMS to announce annual fees in a yearly **Federal Register** notice, starting with the effective date of this rule and for subsequent years, by June 1 each year or as required by specific laws. The fee rates will be effective at the beginning of the following fiscal year, crop year, or as required by specific laws and identified in the yearly notice. The yearly notice will include all rates charged by AMS including some that are not currently part of regulations. The yearly notice will include a per-hour rate and, in some instances, the equivalent per-unit cost. The per-unit cost will be provided to facilitate understanding of the costs associated with the services to the industries that historically use a unit-cost basis for payment. In those cases where per-unit cost is necessary, the formulas will have an additional step to convert per hour costs to per unit costs. This process is currently followed for cotton and some fruit and vegetable user fee services.

Travel costs are also part of the costs that are charged for user fee services. Currently, in some instances, travel costs are already included in the fee charged for service. In other instances, travel costs are added to the fee. In both instances, travel costs are charged to the recipient of the service. The annual notice will maintain the same procedure currently used for recovering travel costs.

AMS is also making several administrative changes and corrections to language in the regulations that is obsolete, such as changing "diskette" to "electronic means".

Definitions

In order to provide additional clarity, AMS defines the following terms used throughout this document as follows:

Bad Debt—Accounts receivable that will likely remain uncollectable and will be written off.

Benefits—various non-wage compensation provided to employees in addition to their normal wages or salaries. Examples of items included in this category are health and unemployment insurance, retirement,

workers compensation, Thrift Savings Plan contributions, and other similar compensation.

Cost of Living Adjustment—the cost of maintaining a certain standard of living based on the economic assumptions in the Office of Management and Budget (OMB), "Update to Civilian Position Full Fringe Benefit Cost Factor, Federal Pay Raise Assumptions, and Inflation Factors used in OMB Circular A-76, Performance of Commercial Activities".

Direct Hours—the regular hours worked by employees of the Agency. This does not include overtime or holiday hours.

Direct Pay—monetary compensation paid to employees of AMS for work performed. Pay is based on the U.S. Office of Personnel Management pay rate tables. It may include night and Sunday differential costs.

Holiday—the official days of the calendar year established by law (5 U.S.C. 6103) or identified by Executive Order as Federal holidays.

Hour—measure by which grading, certification, inspection, classification, laboratory or other services cost is based and expenses are charged.

Indirect Cost—this cost includes program and AMS activities that support the services provided to the industry. Another common term for this cost category is "overhead".

Operating Reserve—funds above expected obligations required to effectively manage uncertainties in demand and cash flow timing.

Operating Cost—costs attributed to performing grading, inspection, certification, or laboratory services duties (i.e. training, equipment, and other such costs), plus operating reserve, plus indirect costs.

Overtime—hours worked in excess of the approved schedule. Work performed after the first 8 hours per day or 40 hours per week is considered overtime.

Regular Rate—the cost per hour for work provided in accordance with an applicant contract. Under Federal labor laws, this rate applies to the first 8 hours per day, or first 40 hours worked per week by AMS employees.

Unit—any measurement that there is one of. For example, one bale of cotton or one truck load of vegetables.

Formulas for Regular, Overtime, and Holiday Rates

With this rulemaking, AMS amends its regulations to provide a set of standardized formulas by which fees are calculated. The methodology used to calculate and implement the fees charged by AMS user-funded programs will be specified in 7 CFR parts 27, 28, 29, 51, 52, 54, 56, 58, 62, 70, 75, and 91.

AMS will use these formulas to calculate annual fee rates starting with the effective date of this rule and for subsequent years. AMS will publish the specific formulas used to calculate service fees. AMS intends to announce the actual annual fee rates in a **Federal Register** notice by June 1 each year or as required by specific laws. These fees will be effective at the beginning of the following fiscal year, crop year, or as required by specific laws.

Salary, hours, and most rates used in the formulas will be based on the prior fiscal year's (or applicable accounting period or historical data) actual costs and hours. AMS will round the final rates up to make the amounts divisible by the quarter hour (15 minutes). Fifteen minutes will be the minimum charge for services covered by these rates.¹ Travel costs may be part of a fee or may be added to the calculated fee.

Currently, some fees are charged on a per unit basis and others are charged on a per hour basis. AMS will continue to provide costs based on a per hour and per unit basis to maintain consistency. For cotton and some fruit and vegetable programs, per unit costs are determined after converting the hourly costs to units.

AMS is establishing the following formulas:

Regular Rate—The total AMS grading, inspection, certification, classification, audit, or laboratory service program personnel direct pay divided by direct hours for the previous year, which is then multiplied by the next year's percentage of cost of living increase, plus the benefits rate, plus the operating rate, plus the allowance for bad debt rate. If applicable, travel expenses may also be added to the cost of providing the service.

An example of the calculation will look like this: [FY 2013 Direct Pay divided by Total Direct Hours (\$2,663,407/82,985) = \$32.10, plus (\$32.10 * 1.7% (2014 cost of living increase)) = \$32.64 + \$10.04 (benefits rate) + \$28.90 (operating rate) + \$.01 (bad debt allowance rate) = \$71.59 (rounded to \$71.60); rounding is done to reflect billable quarter hour increments of 15 minutes. If applicable, travel expenses may also be added.

Overtime Rate—The total AMS grading, inspection, certification, classification, audit, or laboratory service program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 1.5, plus the benefits rate,

¹ The current minimum charge for some services covered by these rates is 30 minutes.

plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

An example of the calculation will look like this: [FY 2013 Direct Pay divided by Total Direct Hours (\$2,663,407/82,985) = \$32.10, plus (\$32.10 * 1.7% (2014 cost of living increase)) = \$32.64, multiplied by 1.5 (\$32.64 * 1.5 (overtime rate)) = \$48.96 + \$10.04 (benefits rate) + 28.90 (operating rate) + \$.01 (bad debt allowance rate) = \$87.91 (rounded to \$87.92); rounding is done to reflect billable quarter hour of 15 minutes. If applicable, travel expenses may also be added.

Holiday Rate—The total AMS grading, inspection, certification, classification, audit, or laboratory service program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 2, plus benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

An example of the calculation will look like this: [FY 2013 Direct Pay divided by Total Direct Hours (\$2,663,407/82,985) = \$32.10, plus (\$32.10 * 1.7% (2014 cost of living increase)) = \$32.64, multiplied by 2 (\$32.64 * 2 (double time or Holiday rate)) = \$65.28 + \$10.04 (benefits rate) + \$28.90 (operating rate) + \$.01 (bad debt allowance rate) = \$104.23 (rounded to \$104.24); rounding is done to reflect billable quarter hour increments of 15 minutes. If applicable, travel expenses may also be added.

Formula calculations are based on prior fiscal year's actual costs or historical costs, workload data, projection of expenses impacting program costs, cost of living increase and inflation. Cost of living increases and inflation factors are based on the economic assumptions from 2013–2023 which have been updated in the Office of Management and Budget's (OMB) FY 2014 Mid-Session Review. Rather than codify a reference to this OMB budget document in this rule, each year AMS intends to use the most recent economic factors released by OMB for budget development purposes to determine cost impacts for these user fee activities.

Formulas for the Benefits, Operating, and Allowance for Bad Debt Rates

AMS will derive the components of the formulas above, using previous fiscal year's actual costs/historical costs, as follows:

Benefits Rate—The total AMS grading, inspection, classification, certification, audit, or laboratory service program direct benefits costs divided by the total hours worked (regular, overtime, and holiday), which is then multiplied by the next calendar year's percentage cost of living increase.

An example of the calculation will look like this: [2013 Direct Benefits cost/ (Total hours + Total Overtime hours + Total Holiday hours) (\$819,207/82,985)] = \$9.87, plus (\$9.87 * 1.7% (2014 Cost of Living)) = \$10.04.

Operating Rate—The total AMS grading, inspection, classification, certification, audit, or laboratory service program operating costs divided by total hours worked (regular, overtime, and holiday), which is then multiplied by the percentage of inflation.

An example of the calculation will look like this: [2013 Total Operating Costs/ (Total hours + Total Overtime hours + Total Holiday hours) (\$2,351,857/82,985)] = \$28.34, plus (\$28.34 * 2% (2014 Inflation)) = \$28.90.

Allowance for Bad Debt Rate—Total AMS grading, inspection, classification, certification, audit, or laboratory service program allowance for bad debt divided by total hours worked (regular, overtime, and holiday).

An example of the calculation will look like this: [2013 Total Bad Debt cost/ (Total hours + Total Overtime hours + Total Holiday hours) (\$1,000/82,985)] = \$0.01

As noted above, the formulas reflect that the cost of providing services include both direct and indirect costs. Direct costs include the cost of salaries, employee benefits, and if applicable, travel and some operating costs. Indirect or overhead costs include the cost of program and Agency activities supporting the services provided to the industry. Indirect cost expenditures are allocated across the Agency for each direct hour of grading, inspection, classification, certification, auditing, or laboratory service provided. For purposes of these formulas, indirect costs have been included as part of operating costs.

Comments

AMS received two comments on the proposed rule.

One commenter asked whether the industry will be notified as to the amounts of each factor within the calculation, including the factors within the benefits rate and the operating rate; whether the Department will publish a final hourly rate for regular, overtime, and holiday rates; and when will the new fee schedule become effective and put into practice.

The categories of costs included in each fee were stated in the proposed rule and are part of this final rule. The specific amounts within each factor will not be published in the annual notice. However, this information is available upon request from the specific AMS program. The final hourly rate for regular, overtime, and holiday rates will be part of the annual notice.

Each year, fees will be announced in a notice in the **Federal Register** by June 1 and take effect at the start of the fiscal year, crop year, or as required by specific laws. The yearly notice will identify the start date for each fee. AMS plans to have these rates in place in FY 15.

Another commenter recommended that application of this uniform fee regulation maintain the calculation and reporting of the cotton classing fee on a per sample basis and that the procedure used by the AMS Cotton Division maintain the flexibility with the formula to account for an adequate reserve and projection of classing volume.

As stated in the proposed rule and earlier in this rule, the yearly notice will include a per-hour rate and, in some instances, the equivalent per-unit cost which is the same as per sample basis. The per-unit (or per sample) cost will be provided to facilitate understanding of the costs associated with the services to the industries that historically use a unit-cost basis for payment.

An adequate reserve and work load (volume) are part of the standardized formulas as they have been in the past.

No changes were made to the proposed rule based on comments received.

Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563. The Office of Management and Budget has not reviewed this rule under these Orders.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effect on Tribal governments and will not have significant Tribal implications.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Has no retroactive effect; and (2) does not require administrative proceedings before parties may file suit in court challenging this rule.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

Most small agricultural service firms have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than \$7,000,000. For certain types of businesses (e.g., dairy, egg, and meat processing; handlers of produce), the SBA considers a small entity as those that employ less than 500 employees.

The grading, inspection, certification and auditing services provided under these regulations are voluntary.^{2,3} The benefits of using grading, inspection, certification, auditing, and laboratory services outpace the costs of obtaining these services. These services are used by meat and poultry establishments, fruit and vegetable handlers and processors, egg processing plants, dairy processors, users of cotton and tobacco program services, importers and exporters of the above commodities, and

other interested persons to determine quality and prices of their products.

AMS estimates that approximately 849 entities use voluntary meat grading and certification services. This estimate includes 413 egg, poultry, and rabbit packing plants that use the USDA grade shield. Of these 413 plants, approximately fifteen percent would be considered a small business under the SBA criteria. The remaining 436 entities includes livestock slaughterers, brokers, meat and other processors, distributors, organic certification companies, trade associations, State and Federal entities, and livestock producers and feeders. Of these 436 entities, approximately 70 percent are considered a small business under the SBA criteria.

AMS estimates that 60 cotton merchants use AMS services for cotton futures classification, 20,000 cotton producers and 637 cotton gins use AMS services for normal cotton classification, and 125 tobacco customers use AMS services. Of these entities, approximately 80 percent are considered a small business under the SBA criteria.

AMS estimates that, over the last two fiscal years, we provided user fee services to an average of 2,308 fruit and vegetable companies for fresh products. AMS estimates that, over the last two fiscal years, we provided user fee services to an average of 1,087 fruit and vegetable companies for processed products. We estimate that approximately 98 percent of these 3,395 companies are considered a small business under the SBA criteria. The number of entities referenced above includes those subject to the provisions of the Agricultural Marketing Agreement Act of 1937.

AMS estimates that 360 dairy plants use AMS' dairy grading and inspection services. We believe that approximately 96 percent of these plants are considered a small business under the SBA criteria.

AMS considered the economic impact of this action on these small entities. The formulas will have a minimal impact on entities that request these services. The difference in fee rates are negligible since the costs used in the formulas to calculate the current and future fees will remain the same. For example, it is expected that the Dairy user fee will change from \$76 per hour to \$78 per hour under the proposed formulas. AMS has not updated several of its programs' user fees for a number of years. For those fees that have not been updated recently, there may be a change in fees. These possible changes will be the result of using current economic data and cost estimates to

calculate the fee rates. AMS will take into consideration, when appropriate, economic and industry conditions before adjusting fees. The process will maintain up-to-date fees.

By including the formulas used to calculate annual user fee rates in the regulations, the Agency streamlines the rulemaking process to help ensure that fees are effective at the beginning of each fiscal year or other period as required by law. Fees will cover inflation and national and locality pay raises but will not support any new budgetary initiative. Any cost changes are similar to other changes that the industry would experience because of inflation and wage increases.

The outcome of this rule will be a transparent system for establishing fee rates for all AMS user fee programs, whereby financial and resource needs for continued operation are reviewed on a pre-determined cycle, using established formulas. This will avoid financial crises that occur when reserve funds are rapidly depleted due to unanticipated business events, and will allow the Agency to more quickly adjust the cost of the services it provides. The information will also greatly benefit AMS customers by allowing them to better plan for the cost of AMS services.

The total volume of commodities graded, inspected and certified under the associated regulations in 2012 was approximately 91 billion pounds. An overall increase in cost per pound of product associated with the new fees is estimated at \$.0002. Even in competitive industries such as fruit and vegetables, meat, poultry, dairy and eggs, this amount of increase in costs will have an insignificant impact on profits and processes. Accordingly, AMS certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

This rule does not contain any new information collection or recordkeeping requirements that are subject to the Office of Management and Budget (OMB) approval under the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

E-Government Act

AMS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, et seq.) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Public awareness of all segments of rulemaking and policy development is

² Currently, there is no mandatory inspection and grading of tobacco under the Tobacco Inspection Act (7 U.S.C. 511–511s).

³ Fees charged for inspection of fruits, vegetables, and specialty crops subject to the Agricultural Marketing Agreement Act of 1937 also would be affected by this rule.

important. Consequently, in an effort to ensure that all interested parties, including minorities, women, and persons with disabilities are aware of this rule, AMS will announce it online and make copies of this **Federal Register** publication available through the AMS Web page located at <http://www.ams.usda.gov/AMSV1.0/>. In addition, AMS offers a subscription service which provides automatic and customized access to selected agricultural commodity news and information. Further, each program will make a concerted effort to inform their respective industries while performing inspections and providing services.

Finally, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

List of Subjects

7 CFR Part 27

Commodity futures, Cotton.

7 CFR Part 28

Administrative practice and procedure, Cotton, Reporting and recordkeeping requirements, Warehouses.

7 CFR Part 29

Administrative practice and procedure, Advisory committees, Government publications, Imports, Pesticide and pests, Reporting and recordkeeping requirements, Tobacco.

7 CFR Part 51

Agricultural commodities, Food grades and standards, Fruits, Nuts, Reporting and recordkeeping requirements, Vegetables.

7 CFR Part 52

Food grades and standards, Food labeling, Frozen foods, Fruits, Reporting and recordkeeping requirements, Vegetables.

7 CFR Part 54

Food grades and standards, Food labeling, Meat and meat products, Poultry and poultry products.

7 CFR Part 56

Eggs and egg products, Food grades and standards, Food labeling, Reporting and recordkeeping requirements.

7 CFR Part 58

Dairy products, Food grades and standards, Food labeling, Reporting and recordkeeping requirements.

7 CFR Part 62

Food grades and standards, Food labeling, Meat and meat products.

7 CFR Part 70

Food grades and standards, Food labeling, Poultry and poultry products, Rabbits and rabbit products, Reporting and recordkeeping requirements.

7 CFR Part 75

Administrative practice and procedure, Agricultural commodities, Reporting and recordkeeping requirements, Seeds, Vegetables.

7 CFR Part 91

Administrative practice and procedure, Agricultural commodities, Laboratories, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR chapter I is amended as follows:

PART 27—COTTON CLASSIFICATION UNDER COTTON FUTURES LEGISLATION

■ 1. The authority citation for part 27 continues to read as follows:

Authority: 7 U.S.C. 15b, 7 U.S.C. 473a–b, 7 U.S.C. 1622(g).

■ 2. Revise § 27.80 by adding paragraphs (a), (b), and (c) and removing paragraph (d) to read as follows:

§ 27.80 Fees; review classification, futures classification and supervision.

* * * * *

(a) For each calendar year, AMS will calculate the rate for services, per hour per program employee using the following formulas:

(1) *Regular rate.* The total AMS grading or classification program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase, plus the benefits rate, plus the operating rate, plus the allowance for bad debt rate. If applicable, travel expenses may also be added to the cost of providing the service.

(2) *Overtime rate.* The total AMS grading or classification program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 1.5 plus the benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

(3) *Holiday rate.* The total AMS grading or classification program personnel direct pay divided by direct hours which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 2, plus the benefits rate, plus the operating rate,

plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

(b) For each calendar year, based on historical costs, AMS will calculate the benefits, operating, and allowance for bad debt components of the regular, overtime and holiday rates as follows:

(1) *Benefits rate.* The total AMS grading or classification program direct benefits costs divided by the total hours (regular, overtime, and holiday) worked, which is then multiplied by the next calendar year's percentage cost of living increase. Some examples of direct benefits are health insurance, retirement, life insurance, and Thrift Savings Plan (TSP) retirement basic and matching contributions.

(2) *Operating rate.* The total AMS grading or classification program operating costs divided by total hours (regular, overtime, and holiday) worked, which is then multiplied by the percentage of inflation.

(3) *Allowance for bad debt rate.* Total AMS grading or classification program allowance for bad debt divided by total hours (regular, overtime, and holiday) worked.

(c) *Basis.* The calendar year cost of living expenses and percentage of inflation factors used in the formulas in this section are based on the most current Office of Management and Budget's Presidential Economic Assumptions.

■ 3. Revise § 27.81 to read as follows:

§ 27.81 Fees; certificates.

For each new certificate issued in substitution for a prior certificate at the request of the holder thereof, for the purpose of business convenience, or when made necessary by the transfer of cotton under the supervision of any exchange inspection agency as provided in § 27.73, the person making the request shall pay a fee determined as described in § 27.80.

PART 28—COTTON CLASSING, TESTING, AND STANDARDS

Subpart A—Regulations Under the United States Cotton Standards Act

■ 4. The authority citation for part 28, subpart A, continues to read as follows:

Authority: 7 U.S.C. 55 and 61.

■ 5. Revise § 28.116 to read as follows:

§ 28.116 Amounts of fees for classification; exemption.

(a) For the classification of any cotton or samples, the person requesting the services shall pay a fee, based on the description that follows, subject to the

additional fee provided by paragraph (c) of this section.

(1) For each calendar year, AMS will calculate the rate for services per hour per program employee using the following formulas:

(i) *Regular rate.* The total AMS grading or classification program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase, plus the benefits rate, plus the operating rate, plus the allowance for bad debt rate. If applicable, travel expenses may also be added to the cost of providing the service.

(ii) *Overtime rate.* The total AMS grading or classification program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 1.5 plus the benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

(iii) *Holiday rate.* The total AMS grading or classification program personnel direct pay divided by direct hours which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 2, plus benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

(2) For each calendar year, based on historical costs, AMS will calculate the benefits, operating, and allowance for bad debt components of the regular, overtime and holiday rates as follows:

(i) *Benefits rate.* The total AMS grading or classification program direct benefits costs divided by the total hours (regular, overtime, and holiday) worked, which is then multiplied by the next calendar year's percentage cost of living increase. Some examples of direct benefits are health insurance, retirement, life insurance, and Thrift Savings Plan (TSP) retirement basic and matching contributions.

(ii) *Operating rate.* The total AMS grading or classification program operating costs divided by total hours (regular, overtime, and holiday) worked, which is then multiplied by the percentage of inflation.

(iii) *Allowance for bad debt rate.* Total AMS grading or classification program allowance for bad debt divided by total hours (regular, overtime, and holiday) worked.

(3) The calendar year cost of living expenses and percentage of inflation factors used in the formulas in this section are based on the most current

Office of Management and Budget's Presidential Economic Assumptions.

(b) When a comparison is requested of any samples with a type or with other samples, the fees prescribed in paragraph (a) of this section shall apply to every sample involved, including each of the samples of which the type is composed.

(c) An additional fee based on current shipping rates shall be assessed for returning samples unless the request for service is so worded that the samples become government property immediately after classification.

(d) For any review of classification or comparison of any cotton, the fees prescribed in paragraph (a) of this section shall apply. The additional fee prescribed in paragraph (c) of this section is not applicable to review of classification if made on the same sample as the original class or comparison.

■ 6. Revise § 28.117 to read as follows:

§ 28.117 Fee for new memorandum or certificate.

For each new memorandum or certificate issued in substitution for a prior memorandum or certificate at the request of the holder, thereof, on account of the breaking or splitting of the lot of cotton covered thereby or otherwise for his business convenience, the person requesting such substitution shall pay a fee determined as described in § 28.116. If the memorandum is provided by electronic means, the fee shall be determined using the same provisions.

■ 7. Revise § 28.122 to read as follows:

§ 28.122 Fee for practical classing examination.

The fee for the practical classing examination for cotton shall be determined as described in § 28.116. Any applicant who passes the examination may be issued a certificate indicating this accomplishment. Any person who fails to pass the examination may be reexamined. The fee for this practical reexamination will be determined as described in § 28.116.

Subpart D—Cotton Classification and Market News Service for Producers

■ 8. The authority citation for part 28, subpart D, continues to read as follows:

Authority: 7 U.S.C. 51–65; 7 U.S.C. 471–476.

■ 9. Amend § 28.909 by revising paragraph (b) to read as follows:

§ 28.909 Costs.

* * * * *

(b) The cost of High Volume Instrument (HVI) cotton classification service to producers will be based on formulas set forth in § 28.116. The proceeds of the sale of cotton samples shall be used to defray the costs of providing the service under this subpart.

* * * * *

■ 10. Revise § 28.910 to read as follows:

§ 28.910 Classification of samples and issuances of classification data.

(a)(1) The samples submitted as provided in the subpart shall be classified by employees of the Division, and classification memoranda showing the official quality determination of each sample according to the official cotton standards of the United States shall be issued by any one of the following methods at no additional charge:

(i) Electronic means; or
(ii) Telecommunications, with all long distance telephone line charges paid by the receiver of data.

(2) When an additional copy of the classification memorandum is issued by any method listed in paragraph (a)(1) of this section, there will be a charge determined as described in § 28.116. If provided as an additional method of data transfer, the minimum fee for each method issued shall also be determined as described in § 28.116.

(b) Owners of cotton, other than producers, may receive classification data showing the official quality determination of each sample by means of telecommunications from a central database to be maintained by the Division. The fee for this service shall be determined as described in § 28.116, with all communication charges paid by the receiver of data.

(c) Upon request of an owner of cotton for which classification memoranda have been issued under the subpart, a new memorandum shall be issued for the business convenience of such owner without the reclassification of the cotton. Such rewritten memorandum shall bear the date of its issuance and the date or inclusive dates of the original classification. The per-hour fee for a new memorandum shall be determined according to § 28.116, with a minimum per-sheet fee determined under the same provisions.

■ 11. Amend § 28.911 by revising paragraph (a) and the last sentence in paragraph (b) to read as follows:

§ 28.911 Review classification.

(a) A producer may request one review classification for each bale of eligible cotton. The fee for review

classification shall be determined based on the formulas in § 28.116.

(b) * * * Producers who request return of their samples after classing will pay a fee determined based on the formulas in § 28.116.

PART 29—TOBACCO INSPECTION

■ 12. The authority citation for part 29 is revised to read as follows:

Authority: 7 U.S.C. 511–511s.

■ 13. Amend § 29.123 by:

■ a. Revising the first sentence of paragraph (a);

■ b. Revising paragraph (b);

■ c. Redesignating paragraphs (c), (d), and (e) as paragraphs (d), (e), and (f), respectively;

■ d. Adding new paragraph (c); and

■ e. Revising newly redesignated paragraph (d).

The revisions and addition read as follows:

§ 29.123 Fees and charges.

* * * * *

(a) *Mandatory inspection.* For each year, AMS will calculate the rate for services, per hour per program employee as described in § 29.123(b) and (c). * * *

(b) *Domestic permissive inspection and certification*—(1) *Regular rate.* The total AMS grading, inspection, or sampling program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase, plus the benefits rate, plus the operating rate, plus the allowance for bad debt rate. If applicable, travel expenses may also be added to the cost of providing the service.

(2) *Overtime rate.* The total AMS grading, inspection, or sampling program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 1.5 plus the benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

(3) *Holiday rate.* The total AMS grading, inspection, or sampling program personnel direct pay divided by direct hours which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 2, plus benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

(4) *Applicability.* The fees in paragraphs (b)(1) through (3) of this

section shall be applicable for hogshead, bale cases, or sample inspections.

(c)(1) For each calendar year, based on previous fiscal year/historical actual costs, AMS will calculate the benefits, operating, and allowance for bad debt components of the regular, overtime and holiday rates as follows:

(i) *Benefits rate.* The total AMS grading, inspection, or sampling program direct benefits costs divided by the total hours (regular, overtime, and holiday) worked, which is then multiplied by the next calendar year's percentage cost of living increase. Some examples of direct benefits are health insurance, retirement, life insurance, and Thrift Savings Plan (TSP) retirement basic and matching contributions.

(ii) *Operating rate.* The total AMS grading, inspection, or sampling program operating costs divided by total hours (regular, overtime, and holiday) worked, which is then multiplied by the percentage of inflation.

(iii) *Allowance for bad debt rate.* Total AMS grading, inspection, or sampling program allowance for bad debt divided by total hours (regular, overtime, and holiday) worked.

(2) The calendar year cost of living expenses and percentage of inflation factors used in the formulas in this section are based on the most recent Office of Management and Budget's Presidential Economic Assumptions.

(d) *Export permissive inspection and certification.* The inspection and certification fee for export tobacco will be determined as described in § 29.123(b) and (c).

* * * * *

■ 14. Amend § 29.500 by revising the first sentence of paragraph (a) and revising paragraphs (b) and (c) to read as follows:

§ 29.500 Fees and charges for inspection and acceptance of imported tobacco.

(a) The fee for inspection of imported tobacco will be determined as described in § 29.123 and shall be paid by the importer. * * *

(b) The fee for sampling, accepting, and certification of imported flue-cured and burley tobacco for prohibited pesticide residues will be determined as described in § 29.123 and shall be paid by the importer.

(c) The fee for accepting imported flue-cured and burley tobacco not accompanied by a certification that it is free of prohibited pesticide residues will be determined as described in § 29.123. Fees for services rendered shall be remitted by check or draft in accordance with a statement issued by the Director,

and shall be made payable to "Agricultural Marketing Service."

PART 51—FRESH FRUITS, VEGETABLES AND OTHER PRODUCTS (INSPECTION, CERTIFICATION, AND STANDARDS)

■ 15. The authority citation for part 51 continues to read as follows:

Authority: 7 U.S.C. 1621–1627.

■ 16. Revise § 51.38 to read as follows:

§ 51.38 Basis for fees and rates.

(a) For each calendar year, AMS will calculate the rate for services, per hour per program employee using the following formulas:

(1) *Regular rate.* The total AMS inspection program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase, plus the benefits rate, plus the operating rate, plus the allowance for bad debt rate. If applicable, travel expenses may also be added to the cost of providing the service.

(2) *Overtime rate.* The total AMS inspection program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 1.5 plus the benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

(3) *Holiday rate.* The total AMS inspection program personnel direct pay divided by direct hours which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 2, plus benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

(b)(1) For each calendar year, based on previous fiscal year/historical actual costs, AMS will calculate the benefits, operating, and allowance for bad debt components of the regular, overtime and holiday rates as follows:

(i) *Benefits rate.* The total AMS inspection program direct benefits costs divided by the total hours (regular, overtime, and holiday) worked, which is then multiplied by the next calendar year's percentage cost of living increase. Some examples of direct benefits are health insurance, retirement, life insurance, and Thrift Savings Plan (TSP) retirement basic and matching contributions.

(ii) *Operating rate.* The total AMS inspection program operating costs divided by total hours (regular,

overtime, and holiday) worked, which is then multiplied by the percentage of inflation.

(iii) *Allowance for bad debt rate.* Total allowance for bad debt divided by total hours (regular, overtime, and holiday) worked.

(2) The calendar year cost of living expenses and percentage of inflation factors used in the formulas in this section are based on the most recent Office of Management and Budget's Presidential Economic Assumptions.

(c) When an inspection is delayed because product is not available or readily accessible, a charge for waiting time shall be determined using the formulas in this section.

PART 52—PROCESSED FRUITS AND VEGETABLES, PROCESSED PRODUCTS THEREOF, AND OTHER PROCESSED FOOD PRODUCTS

■ 17. The authority citation for part 52 continues to read as follows:

Authority: 7 U.S.C. 1621–1627.

§ 52.2 [Amended]

■ 18. Amend § 52.2 by removing the definition of “In-plant sampler”.

■ 19. Revise § 52.42 to read as follows:

§ 52.42 Schedule of fees.

(a) For each calendar year, AMS will calculate the rate for services, per hour per program employee using the following formulas:

(1) *Regular rate.* The total AMS inspection program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase, plus the benefits rate, plus the operating rate, plus the allowance for bad debt rate. If applicable, travel expenses may also be added to the cost of providing the service.

(2) *Overtime rate.* The total AMS inspection program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 1.5 plus the benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

(3) *Holiday rate.* The total AMS inspection program personnel direct pay divided by direct hours which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 2, plus benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

(b) For each calendar year, based on previous fiscal year/historical actual costs, AMS will calculate the benefits, operating, and allowance for bad debt components of the regular, overtime and holiday rates as follows:

(1) *Benefits rate.* The total AMS inspection program direct benefits costs divided by the total hours (regular, overtime, and holiday) worked, which is then multiplied by the next calendar year's percentage cost of living increase. Some examples of direct benefits are health insurance, retirement, life insurance, and Thrift Savings Plan (TSP) retirement basic and matching contributions.

(2) *Operating rate.* The total AMS inspection program operating costs divided by total hours (regular, overtime, and holiday) worked, which is then multiplied by the percentage of inflation.

(3) *Allowance for bad debt rate.* Total AMS inspection program allowance for bad debt divided by total hours (regular, overtime, and holiday) worked.

(c) The calendar year cost of living expenses and percentage of inflation factors used in the formulas in this section are based on the most recent Office of Management and Budget's Presidential Economic Assumptions.

■ 20. Revise § 52.50 to read as follows:

§ 52.50 Travel and other expenses.

Charges may be assessed to cover the cost of travel time incurred in connection with the performance of any inspection service, including appeal inspections, as described in § 52.42. This includes time spent waiting for transportation as well as time spent traveling, but not to exceed eight hours of travel time for any one person for any one day: And provided further, that if travel is by common carrier, no hourly charge may be made for travel time outside the employee's official work hours.

■ 21. Amend § 52.51 by revising paragraphs (a), (b), (c), and (d) to read as follows:

§ 52.51 Charges for inspection services on a contract basis.

(a) The Administrator may enter into contracts with applicants to perform continuous inspection services or other types of inspection services pursuant to the regulations in this part and other requirements as prescribed by the Administrator in such contract, and the charges for such inspection service provided in such contracts shall be based on such basis as will reimburse the Agricultural Marketing Service of the Department for the full cost of

rendering such inspection service as described in § 52.42.

(b) The Administrator may enter into a written memorandum of understanding or contract, whichever may be appropriate, with any administrative agency charged with the administration of a marketing agreement or a marketing order effective pursuant to the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 *et seq.*) for the making of inspections pursuant to said agreement or order on such basis as will reimburse the Agricultural Marketing Service of the Department for the full cost of rendering such inspection service based on the formulas in § 52.42. Likewise, the Administrator may enter into a written memorandum of understanding or contract, whichever may be appropriate, with an administrative agency charged with an administration of a similar program operated pursuant to the laws of any State.

(c) Charges for year-round in-plant inspection services on a contract basis will be billed to the applicant monthly for all hours worked with a minimum of 40 hours per week for each inspector assigned to perform the inspection services. Charges for work performed in excess of an employee's regular work schedule will be calculated as described in § 52.42(a)(2).

(d) Charges for less than year-round in-plant inspection services (four or more consecutive 40 hour weeks) on a contract basis will be billed to the applicant monthly for all hours with a minimum of 40 hours for each inspector assigned to perform the inspection services and will be calculated based on the formulas in § 52.42.

* * * * *

PART 54—MEATS, PREPARED MEATS, AND MEAT PRODUCTS (GRADING, CERTIFICATION, AND STANDARDS)

■ 22. The authority citation for part 54 continues to read as follows:

Authority: 7 U.S.C. 1621–1627.

§ 54.6 [Amended]

■ 23. Amend § 54.6 in paragraph (c)(2), in the first sentence, by removing the phrase “as provided in § 54.27(b)” and adding “as provided in § 54.27” in its place.

■ 24. Revise § 54.27 to read as follows:

§ 54.27 Fees and other charges for service.

(a) Fees and other charges equal as nearly as may be to the cost of the services rendered shall be assessed and collected from applicants in accordance

with the following provisions unless otherwise provided in the cooperative agreement under which the services are furnished, or as provided in § 54.6. For each calendar year, AMS will calculate the rate for inspection, grading, or certification services, per hour per program employee using the following formulas:

(1) *Regular rate.* The total AMS grading, inspection, or certification program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase, plus the benefits rate, plus the operating rate, plus the allowance for bad debt rate. If applicable, travel expenses may also be added to the cost of providing the service.

(2) *Overtime rate.* The total AMS grading, inspection, or certification program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 1.5 plus the benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

(3) *Holiday rate.* The total AMS grading, inspection, or certification program personnel direct pay divided by direct hours which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 2, plus benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

(b)(1) For each calendar year, based on previous fiscal year/historical actual costs, AMS will calculate the benefits, operating, and allowance for bad debt components of the regular, overtime and holiday rates as follows:

(i) *Benefits rate.* The total AMS grading, inspection, or certification program direct benefits costs divided by the total hours (regular, overtime, and holiday) worked, which is then multiplied by the next calendar year's percentage cost of living increase. Some examples of direct benefits are health insurance, retirement, life insurance, and Thrift Savings Plan (TSP) retirement basic and matching contributions.

(ii) *Operating rate.* The total AMS grading, inspection, or certification program operating costs divided by total hours (regular, overtime, and holiday) worked, which is then multiplied by the percentage of inflation.

(iii) *Allowance for bad debt rate.* Total AMS grading, inspection, or certification program allowance for bad

debt divided by total hours (regular, overtime, and holiday) worked.

(2) The calendar year cost of living expenses and percentage of inflation factors used in the formulas in this section are based on the most recent Office of Management and Budget's Presidential Economic Assumptions.

(c) *Fees for service on commitment basis.* Minimum fees for service performed under a commitment agreement or an agreement by memorandum shall be on the basis of 8 hours per day, Monday through Friday, excluding Federal legal holidays occurring Monday through Friday on which no grading and certification services are performed. Fees will be based on the formulas in this section. The Agency reserves the right under such a commitment agreement or agreement by memorandum to use any grader assigned to the plant on a commitment basis to perform service for other applicants, as provided in § 54.6(c), crediting the commitment applicant with the number of hours charged to the other applicant, provided the allowable credit hours plus hours actually worked for the applicants do not exceed 8 hours on any day, Monday through Friday, excluding legal holidays.

(d) *Fees for appeal service.* Fees for appeal service shall be determined on the basis of the time of two official graders required to render the service, including the time required for the preparation of certificates and travel of such graders in connection with the performance of the service. *Provided*, that when on appeal it is found that there was error in the original determination equal to or exceeding ten percent of the total number of similar units of the products involved, no charge will be made for the appeal service unless a special agreement therefor was made with the applicant in advance.

(e) *Fees for extra copies of certificates.* In addition to copies of certificates furnished under § 54.14, any financially interested person may obtain not to exceed three copies of any such certificate within one year from its date of issuance upon payment of a fee, and not to exceed three copies of any such certificate at any time thereafter, while a copy of such certificate is on file in the Department. The fee for copies of certificates will be determined using the formulas in this section.

PART 56—VOLUNTARY GRADING OF SHELL EGGS

■ 25. The authority citation for part 56 continues to read as follows:

Authority: 7 U.S.C. 1621–1627.

■ 26. Revise § 56.46 to read as follows:

§ 56.46 On a fee basis.

(a) Unless otherwise provided in this part, the fees to be charged and collected for any service performed, in accordance with this part, on a fee basis shall be based on the applicable formulas specified in this section. For each calendar year or crop year, AMS will calculate the rate for grading or audit services, per hour per program employee using the following formulas:

(1) *Regular rate.* The total AMS grading or audit program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase, plus the benefits rate, plus the operating rate, plus the allowance for bad debt rate. If applicable, travel expenses may also be added to the cost of providing the service.

(2) *Overtime rate.* The total AMS grading or audit program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 1.5 plus the benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

(3) *Holiday rate.* The total AMS grading or audit program personnel direct pay divided by direct hours which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 2, plus benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

(b)(1) For each calendar year, based on previous fiscal year/historical actual costs, AMS will calculate the benefits, operating, and allowance for bad debt components of the regular, overtime and holiday rates as follows:

(i) *Benefits rate.* The total AMS grading or audit program direct benefits costs divided by the total hours (regular, overtime, and holiday) worked, which is then multiplied by the next calendar year's percentage cost of living increase. Some examples of direct benefits are health insurance, retirement, life insurance, and Thrift Savings Plan (TSP) retirement basic and matching contributions.

(ii) *Operating rate.* The total AMS grading or audit program operating costs divided by total hours (regular, overtime, and holiday) worked, which is then multiplied by the percentage of inflation.

(iii) *Allowance for bad debt rate.* Total AMS grading or audit program allowance for bad debt divided by total hours (regular, overtime, and holiday) worked.

(2) The calendar year cost of living expenses and percentage of inflation factors used in the formulas in this section are based on the most recent Office of Management and Budget's Presidential Economic Assumptions.

(c) Fees for grading services will be based on the time required to perform the services. The hourly charges shall include the time actually required to perform the grading, waiting time, travel time, and any clerical costs involved in issuing a certificate.

(d) Fees for audit services will be based on the time and expenses required to perform the audit. The hourly charge shall include the time actually required to perform the audit, waiting time, travel time, and any clerical costs involved in issuing an audit report.

■ 27. Amend § 56.52 by:

- a. Revising the introductory text;
- b. Revising the second sentence of paragraph (a)(1); and
- c. Revising the first sentence of paragraph (a)(2) introductory text.

The revisions read as follows:

§ 56.52 Charges for continuous grading performed on a resident basis.

Fees to be charged and collected for any grading service, other than for an appeal grading, on a resident grading basis, shall be calculated as described in this part. The fees to be charged for any appeal grading shall be as provided in § 56.47.

(a) * * *

(1) * * * The costs for completing the plant survey shall be borne by the applicant on a fee basis as described in § 56.46. * * *

(2) Charges for the cost of each grader assigned to a plant will be calculated as described in § 56.46, except that no charge will be assessed when the assigned grader is temporarily reassigned by AMS to perform grading service for other than the applicant.

* * *

* * * * *

■ 28. Amend § 56.54 by revising the introductory text and paragraph (a)(1) introductory text to read as follows:

§ 56.54 Charges for continuous grading performed on a nonresident basis.

Fees to be charged and collected for grading service on a nonresident grading basis, shall be calculated as described in this part. The fees to be charged for any appeal grading shall be calculated as provided in § 56.47.

(a) * * *

(1) A charge for the salary and other costs, calculated as described in § 56.46, for each grader while assigned to a plant, except that no charge will be made when the assigned grader is temporarily reassigned by AMS to perform grading service for other than the applicant. Charges to plants are as follows:

* * * * *

PART 58—GRADING AND INSPECTION, GENERAL SPECIFICATIONS FOR APPROVED PLANTS AND STANDARDS FOR GRADES OF DAIRY PRODUCTS

■ 29. The authority citation for part 58 continues to read as follows:

Authority: 7 U.S.C. 1621–1627.

■ 30. Revise § 58.39 to read as follows:

§ 58.39 Fees for holiday or other nonworktime.

If an applicant requests that inspection or grading service be performed on a holiday, Saturday, or Sunday or in excess of each 8-hour shift Monday through Friday, the applicant shall be charged for such service at a rate determined using the formulas in § 58.43.

■ 31. Revise § 58.43 to read as follows:

§ 58.43 Fees for inspection, grading, sampling, and certification.

(a) Unless otherwise provided in this part, the fees to be charged and collected for any service performed, in accordance with this part, on a fee basis shall be based on the applicable formulas specified in this section. For each calendar year, AMS will calculate the rate for grading, certification, or inspection services, per hour per program employee using the following formulas:

(1) *Regular rate.* The total AMS grading, certification, or inspection program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase, plus the benefits rate, plus the operating rate, plus the allowance for bad debt rate. If applicable, travel expenses may also be added to the cost of providing the service.

(2) *Overtime rate.* The total AMS grading, certification, or inspection program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 1.5 plus the benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable,

travel expenses may also be added to the cost of providing the service.

(3) *Holiday rate.* The total AMS grading, certification, or inspection program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 2, plus benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

(b) For each calendar year, based on previous fiscal year/historical actual costs, AMS will calculate the benefits, operating, and allowance for bad debt components of the regular, overtime and holiday rates as follows:

(1) *Benefits rate.* The total AMS grading, certification, or inspection program direct benefits costs divided by the total hours (regular, overtime, and holiday) worked, which is then multiplied by the next calendar year's percentage cost of living increase. Some examples of direct benefits are health insurance, retirement, life insurance, and Thrift Savings Plan (TSP) retirement basic and matching contributions.

(2) *Operating rate.* The total AMS grading, certification, or inspection program operating costs divided by total hours (regular, overtime, and holiday) worked, which is then multiplied by the percentage of inflation.

(3) *Allowance for bad debt rate.* Total AMS grading, certification, or inspection program allowance for bad debt divided by total hours (regular, overtime, and holiday) worked.

(c) The calendar year cost of living expenses and percentage of inflation factors used in the formulas in this section are based on the most recent Office of Management and Budget's Presidential Economic Assumptions.

■ 32. Revise § 58.45 to read as follows:

§ 58.45 Fees for continuous resident services.

Charges for the inspector(s) and grader(s) assigned to a continuous resident program shall be calculated using the formulas in § 58.43.

PART 62—LIVESTOCK, MEAT AND OTHER AGRICULTURAL COMMODITIES (QUALITY SYSTEMS VERIFICATION PROGRAMS)

■ 33. The authority citation for part 62 is revised to read as follows:

Authority: 7 U.S.C. 1621–1627.

■ 34. Revise § 62.300 to read as follows:

§ 62.300 Fees and other costs of service.

(a) For each calendar year, AMS will calculate the rate for quality systems verification services, per hour per program employee using the following formulas:

(1) *Regular rate.* The total AMS quality systems verification program (QSVP) personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase, plus the benefits rate, plus the operating rate, plus the allowance for bad debt rate. If applicable, travel expenses may also be added to the cost of providing the service.

(2) *Overtime rate.* The total AMS QSVP personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 1.5 plus the benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

(3) *Holiday rate.* The total AMS QSVP personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 2, plus benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

(b)(1) For each calendar year, based on previous fiscal year/historical actual costs, AMS will calculate the benefits, operating, and allowance for bad debt components of the regular, overtime and holiday rates as follows:

(i) *Benefits rate.* The total AMS QSVP direct benefits costs divided by the total hours (regular, overtime, and holiday) worked, which is then multiplied by the next calendar year's percentage cost of living increase. Some examples of direct benefits are health insurance, retirement, life insurance, and Thrift Savings Plan (TSP) retirement basic and matching contributions.

(ii) *Operating rate.* The total AMS QSVP operating costs divided by total hours (regular, overtime, and holiday) worked, which is then multiplied by the percentage of inflation.

(iii) *Allowance for bad debt rate.* Total AMS QSVP allowance for bad debt divided by total hours (regular, overtime, and holiday) worked.

(2) The calendar year cost of living expenses and percentage of inflation factors used in the formulas in this section are based on the most recent Office of Management and Budget's Presidential Economic Assumptions.

(c) *Transportation costs.* Applicants are responsible for paying actual travel costs incurred to provide QSVP services including but not limited to: Mileage charges for use of privately owned vehicles, rental vehicles and gas, parking, tolls, and public transportation costs such as airfare, train, and taxi service.

(d) *Per diem costs.* The applicant is responsible for paying per diem costs incurred to provide QSVP services away from the auditor's or USDA officials' official duty station(s). Per diem costs shall be calculated in accordance with existing travel regulations (41 CFR, subtitle F—Federal Travel Regulation System, chapter 301).

(e) *Other costs.* When costs, other than those costs specified in paragraphs (a) through (c) of this section, are involved in providing the QSVP services, the applicant shall be responsible for these costs. The amount of these costs shall be determined administratively by the Chief. However, the applicant will be notified of these costs before the service is rendered.

PART 70—VOLUNTARY GRADING OF POULTRY AND RABBIT PRODUCTS

■ 35. The authority citation for part 70 continues to read as follows:

Authority: 7 U.S.C. 1621–1627.

■ 36. Revise § 70.71 to read as follows:

§ 70.71 On a fee basis.

Unless otherwise provided in this part, the fees to be charged and collected for any grading or audit service performed in accordance with this part, on a fee basis shall be based on the applicable formulas specified in this section.

(a) For each calendar year, AMS will calculate the rate for grading and audit services, per hour per program employee using the following formulas:

(1) *Regular rate.* The total AMS grading or audit program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase, plus the benefits rate, plus the operating rate, plus the allowance for bad debt rate. If applicable, travel expenses may also be added to the cost of providing the service.

(2) *Overtime rate.* The total AMS grading or audit program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 1.5 plus the benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be

added to the cost of providing the service.

(3) *Holiday rate.* The total AMS grading or audit program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 2, plus benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

(b)(1) For each calendar year, based on previous fiscal year/historical actual costs, AMS will calculate the benefits, operating, and allowance for bad debt components of the regular, overtime and holiday rates as follows:

(i) *Benefits rate.* The total AMS grading or audit program direct benefits costs divided by the total hours (regular, overtime, and holiday) worked, which is then multiplied by the next calendar year's percentage cost of living increase. Some examples of direct benefits are health insurance, retirement, life insurance, and Thrift Savings Plan (TSP) retirement basic and matching contributions.

(ii) *Operating rate.* The AMS grading or audit program total operating costs divided by total hours (regular, overtime, and holiday) worked, which is then multiplied by the percentage of inflation.

(iii) *Allowance for bad debt rate.* Total AMS grading or audit program allowance for bad debt divided by total hours (regular, overtime, and holiday) worked.

(2) The calendar year cost of living expenses and percentage of inflation factors used in the formulas in this section are based on the most recent Office of Management and Budget's Presidential Economic Assumptions.

(c) Fees for grading services will be based on the time required to perform the services. The hourly charges shall include the time actually required to perform the grading, waiting time, travel time, and any clerical costs involved in issuing a certificate.

(d) Fees for audit services will be based on the time and expenses required to perform the audit. The hourly charge shall include the time actually required to perform the audit, waiting time, travel time, and any clerical costs involved in issuing an audit report.

■ 37. Revise § 70.72 to read as follows:

§ 70.72 Fees for appeal grading or review of a grader's decision.

The costs of an appeal grading, or review of a grader's decision, shall be borne by the appellant on a fee basis at

rates determined based on the formulas in § 70.71. If the appeal grading, or review of a grader's decision discloses that a material error was made in the original determination, no fee or expenses will be charged.

■ 38. Amend § 70.76 by revising the introductory text and the first sentence of paragraph (a)(1) introductory text to read as follows:

§ 70.76 Charges for continuous poultry grading performed on a nonresident basis.

Fees to be charged and collected for grading service on a nonresident grading basis shall be based on the formulas provided in this part. The fees to be charged for any appeal grading shall be as provided in § 70.72.

(a) * * *

(1) A charge for the salary and other costs, based on § 70.71, for each grader while assigned to a plant, except that no charge will be made when the assigned grader is temporarily reassigned by AMS to perform grading service for other than the applicant. * * *

* * * * *

■ 39. Amend § 70.77 by revising the introductory text and paragraphs (a)(1) and (2) to read as follows:

§ 70.77 Charges for continuous poultry or rabbit grading performed on a resident basis.

Fees to be charged and collected for any grading service on a resident grading basis and for an appeal grading shall be determined based on the formulas in § 70.71.

(a) * * *

(1) When a signed application for service has been received, the State supervisor or the supervisor's assistant shall complete a plant survey pursuant to § 70.34. The costs for completing the plant survey shall be borne by the applicant on a fee basis based on the formulas in § 70.71. No charges will be assessed when the application is required because of a change in name or ownership. If service is not installed within 6 months from the date the application is filed, or if service is inactive due to an approved request for removal of a grader(s) for a period of 6 months, the application will be considered terminated, but a new application may be filed at any time. In addition, there will be a charge of \$300 if the application is terminated at the request of the applicant for reasons other than for a change in location within 12 months from the date of the inauguration of service.

(2) A charge for the salary and other costs, as specified in this part, for each grader while assigned to a plant, except that no charge will be made when the

assigned grader is temporarily reassigned by AMS to perform grading service for other than the applicant.

* * * * *

PART 75—REGULATIONS FOR INSPECTION AND CERTIFICATION OF QUALITY OF AGRICULTURAL AND VEGETABLE SEEDS

■ 40. The authority citation for part 75 continues to read as follows:

Authority: 7 U.S.C. 1622 and 1624.

■ 41. Revise § 75.41 to read as follows:

§ 75.41 General.

Fees and charges for inspection or certification services performed by Federal employees shall cover the cost of performing the service. Fees shall be for actual time required to render the service.

(a) For each calendar year, AMS will calculate the rate for inspection or certification services, per hour per program employee using the following formulas:

(1) *Regular rate.* The total AMS inspection or certification program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase, plus the benefits rate, plus the operating rate, plus the allowance for bad debt rate. If applicable, travel expenses may also be added to the cost of providing the service.

(2) *Overtime rate.* The total AMS inspection or certification program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 1.5 plus the benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

(3) *Holiday rate.* The total AMS inspection or certification program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 2, plus benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

(b) For each calendar year, based on previous fiscal year/historical actual costs, AMS will calculate the benefits, operating, and allowance for bad debt components of the regular, overtime and holiday rates as follows:

(1) *Benefits rate.* The total AMS inspection or certification program direct benefits costs divided by the total

hours (regular, overtime, and holiday) worked, which is then multiplied by the next calendar year's percentage cost of living increase. Some examples of direct benefits are health insurance, retirement, life insurance, and Thrift Savings Plan (TSP) retirement basic and matching contributions.

(2) *Operating rate.* The total AMS inspection or certification program operating costs divided by total hours (regular, overtime, and holiday) worked, which is then multiplied by the percentage of inflation.

(3) *Allowance for bad debt rate.* Total AMS inspection or certification program allowance for bad debt divided by total hours (regular, overtime, and holiday) worked.

(c) The calendar year cost of living expenses and percentage of inflation factors used in the formulas in this section are based on the most recent Office of Management and Budget's Presidential Economic Assumptions.

■ 42. Amend § 75.42 by revising paragraph (b) to read as follows:

§ 75.42 Sampling and sealing.

* * * * *

(b) When onsite inspection services are performed by Federal employees at the request of the applicant, charges will be based on the formulas in § 75.41.

■ 43. Amend § 75.43 by revising paragraphs (a) and (c) to read as follows:

§ 75.43 Laboratory testing.

* * * * *

(a) Fees assessed based on the formulas in § 75.41.

* * * * *

(c) The fee for a preliminary report issued prior to completion of testing shall be assessed in accordance with paragraph (a) of this section.

PART 91—SERVICES AND GENERAL INFORMATION

■ 44. The authority citation for part 91 continues to read as follows:

Authority: 7 U.S.C. 1622, 1624.

■ 45. Amend § 91.37 by:

- a. Revising paragraphs (a) and (b);
- b. Removing paragraph (c); and
- c. Redesignating paragraphs (d) and (e) as paragraphs (c) and (d), respectively.

The revisions read as follows:

§ 91.37 Standard hourly fee rate for laboratory testing, analysis, and other services.

(a) For each fiscal year, AMS will calculate the rate for laboratory testing, analysis, and other services, per hour per program employee using the following formulas:

(1) *Regular rate.* The total AMS laboratory service program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase, plus the benefits rate, plus the operating rate, plus the allowance for bad debt rate. If applicable, travel expenses may also be added to the cost of providing the service.

(2) *Overtime rate.* The total AMS laboratory service program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 1.5 plus the benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

(3) *Holiday rate.* The total AMS laboratory service program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 2, plus benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

(b)(1) For each calendar year, based on previous fiscal year/historical actual costs, AMS will calculate the benefits, operating, and allowance for bad debt components of the regular, overtime and holiday rates as follows:

(i) *Benefits rate.* The total AMS laboratory service program direct benefits costs divided by the total hours (regular, overtime, and holiday) worked, which is then multiplied by the next calendar year's percentage cost of living increase. Some examples of direct benefits are health insurance, retirement, life insurance, and Thrift Savings Plan (TSP) retirement basic and matching contributions.

(ii) *Operating rate.* The total AMS laboratory service program operating costs divided by total hours (regular, overtime, and holiday) worked, which is then multiplied by the percentage of inflation.

(iii) *Allowance for bad debt rate.* Total AMS laboratory service program allowance for bad debt divided by total hours (regular, overtime, and holiday) worked.

(2) The calendar year cost of living expenses and percentage of inflation factors used in the formulas in this section are based on the most recent Office of Management and Budget's Presidential Economic Assumptions.

* * * * *

■ 46. Amend § 91.38 by revising paragraph (a) to read as follows:

§ 91.38 Additional fees for appeal of analysis.

(a) The applicant for appeal sample testing will be charged a fee based on the formulas in § 91.37.

* * * * *

■ 47. Amend § 91.39 by revising paragraph (a) to read as follows:

§ 91.39 Premium hourly fee rates for overtime and legal holiday service.

(a) When analytical testing in a Science and Technology facility requires the services of laboratory personnel beyond their regularly assigned tour of duty on any day or on a day outside the established schedule, such services are considered as overtime work. When analytical testing in a Science and Technology facility requires the services of laboratory personnel on a Federal holiday or a day designated in lieu of such a holiday, such services are considered holiday work. Laboratory analyses initiated at the request of the applicant to be rendered on Federal holidays, and on an overtime basis will be charged fees based on the formulas in § 91.37.

* * * * *

Dated: November 5, 2014.

Erin M. Morris,

Associate Administrator, Agricultural Marketing Service.

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FEDERAL RESERVE SYSTEM

12 CFR Chapter II

[Docket No. OP-1478]

Policy on Payment System Risk

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Policy statement.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) has adopted revisions to part I of its *Federal Reserve Policy on Payment System Risk* (PSR policy) to reflect the prevailing international standards, the *Principles for Financial Market Infrastructures* (PFMI), which were developed by the Committee on Payment and Settlement Systems (CPSS) and the Technical Committee of the International Organization of Securities Commissions (IOSCO) and published in April 2012, and the supervisory framework for designated financial market utilities (FMUs) established in Title VIII of the

Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Dodd-Frank Act or Act). The Board also made conforming and technical changes to part I of the PSR policy.

DATES: The Board will be guided by the PSR policy revisions when exercising the authorities discussed therein as of December 31, 2014, with the exception of the following measures, which the Board would expect to be met on or before December 31, 2015: Transparency, set forth in section I.B.2; establishing plans for recovery and orderly wind-down as necessary to meet the expectations of principle 3; establishing rules and procedures that explicitly address uncovered credit losses and liquidity shortfalls as necessary to meet the expectations of principles 4 and 7, respectively; maintaining sufficient liquid net assets funded by equity and a viable plan for raising additional equity as necessary to meet the expectations of principle 15; and managing risks arising in tiered participation arrangements as necessary to meet the expectations of principle 19.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In adopting the PSR policy, the Board's objectives have been to foster the safety and efficiency of payment, clearing, and settlement systems. Part I of the policy sets forth the Board's views, and related principles and minimum standards, regarding the management of risks in and transparency of payment, clearing, and settlement systems, including those operated by the Federal Reserve Banks (Reserve Banks).¹ Part I of the policy incorporates relevant international risk-management standards developed by central banks and market regulators as the baseline for its expectations for payment, clearing, and settlement systems.² Part I is not intended to exert

¹ Part II governs the provision of intraday credit in accounts at the Reserve Banks and sets out the general methods used by the Reserve Banks to control their intraday credit exposures.

² Prior to this notice, part I of the PSR policy incorporated the international standards for payment, clearing, and settlement systems set out

or create supervisory or regulatory authority over any particular class of institutions or arrangements where the Board does not have such authority.

In January 2014, the Board requested comment on proposed revisions to part I of the PSR policy.³ The key aspects of the proposal were (1) revising the Board's existing minimum risk-management standards in the PSR policy to reflect the PFMI, which now represents the relevant set of international standards;⁴ (2) including all central securities depositories, securities settlement systems, and central counterparties (CCPs) in the scope of part I of the PSR policy; (3) expanding the scope of part I of the PSR policy to include trade repositories; (4) establishing six mutually exclusive categories of financial market infrastructures (FMIs) and clarifying the Board's risk-management expectations for FMIs in each category; (5) replacing the existing self-assessment framework with a broader disclosure expectation; and (6) recognizing responsibility E from the PFMI, in addition to other relevant international guidance, as the basis for cooperation with other authorities in overseeing FMIs. The proposed changes did not affect part II of the PSR policy.

The Board proposed revisions to the policy to incorporate the new international risk-management standards for financial market infrastructures in the PFMI, including the expectation for FMIs to complete the disclosure framework set out in the December 2012 CPSS-IOSCO report on the *Principles for Financial Market Infrastructures: Disclosure Framework and Assessment Methodology* ("disclosure framework" and "assessment methodology").⁵ The Board also proposed revisions to the policy to reflect the enhanced supervisory framework for designated FMUs as set forth in Title VIII of the Dodd-Frank Act.⁶ In particular, the Board proposed

certain revisions that were necessary to clarify that designated FMUs for which the Board is the Supervisory Agency under Title VIII of the Act are required to comply with Regulation HH and not the risk-management or transparency expectations set out in the policy.⁷ The public comment period for the proposed revisions closed on March 31, 2014.

II. Summary of Comments and Analysis

The Board received three comment letters that were responsive to the January proposal, all from entities that operate designated FMUs.⁹ The Board considered each of the comments on the proposed revisions to the PSR policy in developing its final policy as discussed in more detail below. Except as noted herein, the Board is adopting the policy as proposed.¹⁰

A. Overall Approach To Incorporating the New Standards

The Board proposed to revise part I of the PSR policy by replacing the existing risk-management standards with the 24

a multilateral system for the purpose of transferring, clearing, or settling payments, securities, or other financial transactions among financial institutions or between financial institutions and the person" (12 U.S.C. 5462(6)). FMUs are a subset of FMIs; for example, trade repositories are excluded from the definition of a FMU. Pursuant to section 804 of the Dodd-Frank Act, the Financial Stability Oversight Council (Council) is required to designate those FMUs that the Council determines are, or are likely to become, systemically important. Such a designation by the Council makes an FMU subject to the supervisory framework set out in Title VIII of the Dodd-Frank Act.

⁷ Concurrent with this final policy statement, the Board is adopting final revisions to Regulation HH that take into consideration the PFMI.

⁸ The term "Supervisory Agency" is defined in Title VIII as the "Federal agency that has primary jurisdiction over a designated financial market utility under Federal banking, securities, or commodity futures laws" (12 U.S.C. 5462(8)). Currently, the Board is the Supervisory Agency for two FMUs that have been designated by the Council—The Clearing House Payments Company, L.L.C., on the basis of its role as operator of the Clearing House Interbank Payments System, and CLS Bank International; these designated FMUs are subject to the Regulation HH risk-management standards promulgated by the Board under section 805(a)(1)(A). The Regulation HH standards also apply to any designated FMU for which another Federal banking agency is the appropriate Title VIII Supervisory Agency. At this time, there are no designated FMUs in this category.

⁹ Concurrent with the proposal, the Board issued in a separate **Federal Register** notice a proposal to amend Regulation HH by replacing the existing risk-management standards with a set of standards based on the PFMI and making conforming changes to the definitions (79 FR 3666 (January 22, 2014)). All three commenters addressed the proposed revisions to both part I of the PSR policy and Regulation HH in one letter. Where the commenters addressed specific provisions of Regulation HH that did not appear in the revisions to the PSR policy, the Board addressed those comments only in the notice of final rulemaking for Regulation HH.

¹⁰ In addition, the Board is making several technical edits to the proposed policy. These edits are minor and are not discussed in this notice.

headline standards from the PFMI verbatim. Commenters were generally supportive of the Board's overall approach. One commenter, however, raised two general concerns with respect to the Board's overall approach. The commenter expressed concern that one uniform set of standards that applies to all FMIs and all designs of the same type of FMI does not sufficiently take into account material differences that can be found among the different systems. The commenter also expressed concern that differences in language between the risk-management standards in Regulation HH and in part I of the PSR policy may result in two different sets of risk-management standards for FMIs.

With respect to differences among types of systems, the Board believes that a uniform set of standards is appropriate because, in many instances, FMIs face and must manage certain common risks. Although the design of systems may vary, the flexibility in the standards allows individual FMIs to implement, and supervisors to enforce, the standards appropriately based on the design of and risks that arise in a particular FMI. The Board also believes that a uniform set of standards promotes financial stability because it facilitates effective and consistent risk management across different types of FMIs and markets. For specific risk-management standards in the PSR policy that are applicable only to certain types of FMI, however, those standards are made expressly applicable only to those FMI types (for example, only CCPs are expected to have a risk-based margin system to cover credit risk). For these reasons, the Board continues to believe the overall approach is appropriate.

With respect to the differences in the language between Regulation HH and part I of the PSR policy, the Board continues to believe that such differences are appropriate. Regulation HH is an enforceable rule applicable to designated FMUs other than those supervised by the CFTC or SEC, so additional details from the key considerations and explanatory notes of the PFMI were incorporated in the rule text to provide greater clarity on the Board's expectations. The PSR policy, on the other hand, is a policy statement that provides guidance with respect to the Board's exercise of its other supervisory or regulatory authority over other financial market infrastructures (including those operated by the Federal Reserve Banks) or their participants, its participation in cooperative oversight arrangements for financial market infrastructures, or the provision of intraday credit to eligible Federal

in the CPSS *Core Principles for Systemically Important Payment Systems*, the CPSS-IOSCO *Recommendations for Securities Settlement Systems*, and the CPSS-IOSCO *Recommendations for Central Counterparties*, which are available at <http://www.bis.org/cpmi/publ/d43.pdf>, <http://www.bis.org/cpmi/publ/d46.pdf>, and <http://www.bis.org/cpmi/publ/d64.pdf>, respectively. (Effective September 2014, the CPSS changed its name to the Committee on Payments and Market Infrastructures.)

³ 79 FR 2838 (January 16, 2014).

⁴ The PFMI is available at <http://www.bis.org/cpmi/publ/d101a.pdf>.

⁵ The CPSS-IOSCO report on the *Principles for Financial Market Infrastructures: Disclosure Framework and Assessment Methodology* is available at <http://www.bis.org/cpmi/publ/d106.pdf>.

⁶ The term "financial market utility" is defined in Title VIII as "any person that manages or operates

Reserve account holders. Incorporating the headline standards from the PFMI is consistent with the purpose of the document and the Board's long-standing principles-based approach to its PSR policy. Further, the Board will be guided by the key considerations and the explanatory text of the PFMI, as well as its interpretation of the corresponding provisions of Regulation HH, in its application of the PSR policy. The Board does not intend for the differences in language in the two documents to lead to inconsistent policy results.

B. Overall Approach To Applying the Policy

The proposed revised policy stated that the Board sets out its views regarding management of risks in FMIs in part I of the PSR policy in order to encourage these systems and their primary regulators to take the standards in the policy into consideration in the design, operation, monitoring, and assessment of these systems. One commenter stated that the Board should acknowledge in the final PSR policy that if a regulatory agency other than the Board is the Supervisory Agency for a designated FMU, then the Board would consider compliance by the designated FMU with the corresponding PFMI-based regulations of such Supervisory Agency as sufficient.

In carrying out its Title VIII responsibilities, the Board participates in examinations of designated FMUs by other Supervisory Agencies and provides input to those Agencies with respect to the designated FMU's risk-management practices. Although the Supervisory Agency would apply its own rules in assessing the sufficiency of the designated FMU's compliance, the Board's input will be informed by the principles in the PSR policy as well as the Agency's rules and the general framework of Title VIII of the Dodd-Frank Act. Therefore, the Board will maintain the overall approach of the policy as proposed.

C. Governance

Proposed principle 2 stated that an FMI should have governance arrangements that are clear and transparent, promote the safety and efficiency of the FMI, and support the stability of the broader financial system, other relevant public interest considerations, and the objectives of relevant stakeholders. One commenter noted that public interest considerations is a vague concept, and that private-sector systems should not be required to consider public interest considerations

and should focus exclusively on the needs of participants.

The Board believes that taking public interest considerations into account is consistent with the objectives of Title VIII of the Act to promote robust risk management, promote the safety and soundness of the designated FMU, and reduce systemic risks. For example, public interests may include supporting fair and efficient markets because an FMI that creates inefficiencies in the market may drive market participants toward less-safe alternatives that could increase systemic risks. Market transparency is another public interest consideration that may be relevant because, for example, an FMI that provides information to relevant authorities and the public about payment flows may help to identify and reduce sources of systemic risk. For certain FMIs, stability of the broader financial system may be the only relevant public interest consideration. The final policy retains the text of the principle as proposed.

D. Credit Risk

Proposed principle 4 stated that an FMI should measure, monitor, and manage effectively its credit exposures to its participants and the credit exposures arising from its payment, clearing, and settlement processes. The principle also stated that an FMI should maintain sufficient financial resources to cover its credit exposure to each participant fully with a high degree of confidence. In addition, a CCP that is involved in activities with a more-complex risk profile or that is systemically important in multiple jurisdictions should maintain additional financial resources sufficient to cover a wide range of potential stress scenarios that should include, but not be limited to, the default of the two participants and their affiliates that would potentially cause the largest credit exposure to the CCP in extreme but plausible market conditions (a "cover 2" expectation).

One commenter stated that, in setting a "cover 2" expectation for a particular FMI, the Board should also consider "the proportion of the CCP's clearing activities involving products with complex risk profiles as well as the manner in which the CCP manages those risks." The commenter asked the Board to confirm that the "cover 2" expectation would not be triggered if a CCP has a small amount of activity with a complex risk profile relative to overall activity or if the CCP addresses the added risk incurred, such as through enhanced margin systems. The Board's "cover 2" expectation for a particular

FMI would depend on all relevant facts and circumstances, including the mix of activities with varying risk profiles. The Board believes that the proposed policy language provides sufficient flexibility and has adopted the text of the principle as proposed.

E. Collateral

Proposed principle 5 stated that an FMI that requires collateral to manage its or its participants' credit exposure should accept collateral with low credit, liquidity, and market risks and should set and enforce appropriately conservative haircuts and concentration limits. One commenter supported the flexibility in the wording of the principle and urged that it not be interpreted to exclude the use of equity securities as collateral for equity options. The Board believes that the principle would permit, where appropriate, an FMI to integrate the management of risk from participant positions with the risk from fluctuations in the value of collateral provided by participants. One example would be for a CCP to hold equity securities as collateral for options on those same securities. The final policy retains the text of the principle as proposed.

F. Liquidity Risk

In the proposed policy, the Board defined liquidity risk as "the risk that a counterparty, whether a participant or other entity, will be unable to meet fully its financial obligations when due, although it may be able to do so in the future." The definition went on to explain that an FMI, through its design or operation, may bear or generate liquidity risk in one or more currencies in its payment or settlement process. In this context, liquidity risk may arise between or among the system operator and the participants in the FMI, the system operator and other entities (such as settlement banks, nostro agents, or liquidity providers), the participants in the FMI and other entities, or two or more participants in the FMI.

After further consideration, the Board has added a footnote to the definition of liquidity risk to clarify that the Board believes that deliveries of currency are payments, and FMIs that conduct such activity should consider these deliveries to be payments in the management of liquidity risk. The Board added this footnote to clarify that it does not believe that such deliveries of currency should be treated as physical deliveries under principle 10 in the revised risk-management standards, but rather it would expect an FMI subject to its authority to manage effectively the liquidity risk related to these payments.

G. Settlement Finality

Proposed principle 8 stated that an FMI should provide clear and certain final settlement, at a minimum by the end of the value date. One commenter requested confirmation that the proposed provision would not require an FMI that is a CCP to accelerate its novation of certain noncompetitive transactions, such as backloaded over-the-counter options. The principle applies to an FMI's obligations to deliver funds and other financial instruments, at a minimum, by the end of the value date in accordance with the terms of the underlying contract and does not address the timing of novation. The Board believes that the proposed policy language provides sufficient flexibility, and the final policy retains the text of the principle as proposed.

H. Segregation and Portability

Proposed principle 14 stated that a CCP should have rules and procedures that enable the segregation and portability of positions of a participant's customers and the collateral provided to the CCP with respect to those positions. The Board received two comment letters on this principle that addressed portability and alternative segregation regimes.

Portability. One commenter noted that, while porting positions is a highly desirable result where feasible, there may be scenarios where liquidating positions is preferred. The commenter suggested that the Board allow an FMI to retain broad discretion to liquidate positions promptly where it has determined that timely transfer would not be feasible. The Board interprets the principle, which states that a central counterparty should have rules and procedures that enable the segregation and portability of positions, not to exclude the possibility that liquidation of positions may take place if a timely transfer would not be feasible. The Board believes that the proposed policy language provides sufficient flexibility, and the final policy retains the text of the principle as proposed.

Alternative segregation regimes. One commenter encouraged the Board to state in the policy that different segregation regimes are appropriate for different markets and different classes of market participant. Another commenter requested that the final text of the policy acknowledge the different legal frameworks for cash markets. The Board acknowledges that effective segregation and portability arrangements depend not only on the operational capabilities of the CCP but also on the applicable legal framework. The Board notes that a

CCP serving certain cash markets, for example, may operate in a legal regime that offers the same degree of protection for a participant's customers as the segregation and portability approaches addressed in principle 14 of the PFMI. Where an alternative regime exists, the Board will consider the CCP's assessment of whether the applicable legal or regulatory framework achieves the same degree of protection and efficiency for customers that would otherwise be achieved by segregation and portability arrangements at the CCP level. Additionally, the Board will consider whether the CCP's own rules enable the operation of the relevant legal and regulatory framework.

Where alternative segregation and portability arrangements offer the same degree of protection, proposed principle 14 would not prohibit the use of such arrangements. As noted above, the expectation is that an FMI's rules and procedures enable segregation and portability of positions, and the policy does not prescribe a single means by which this could be achieved. The final policy retains the text of the principle as proposed.

I. General Business Risk

Proposed principle 15 stated that an FMI should identify, monitor, and manage its general business risk and hold sufficient liquid net assets funded by equity to cover potential general business losses so that it can continue operations and services as a going concern if those losses materialize. Further, liquid net assets should at all times be sufficient to ensure a recovery or orderly wind-down of critical operations and services. Commenters generally supported the principle, but made two specific points that are addressed below.

Treatment of Reserve Bank services under the principle. One commenter stated that the Board should ensure that the requirements with respect to principle 15 in Regulation HH for designated FMUs are the same as those imposed on the equivalent Reserve Bank service. The Board expects that the Fedwire Services will meet or exceed the applicable standards set forth in this policy. The Board will be guided by the key considerations and explanatory notes in the PFMI, including the guidance on central bank-operated systems, as well as its interpretation of the corresponding provisions of Regulation HH, in supervising the Fedwire Services. This expectation is consistent with past practice.

Consistent with the previous international standards, the PFMI recognizes that flexibility in

implementation is warranted for central bank-operated systems to meet the objectives of the standards because of central banks' roles as monetary authorities and liquidity providers. As noted in the proposal, the Board will allow flexibility in application of principle 15 on general business risk for the Fedwire Services. A key consideration in principle 15 of the PFMI requires FMIs to maintain viable recovery or orderly wind-down plans that consider general business risk and to hold sufficient liquidity and capital reserves to implement the plans. The Fedwire Services do not face the risk that a business shock would cause the service to wind down in a disorderly manner and disrupt the stability of the financial system. Given the fundamental role of the Fedwire Services in the U.S. financial system, the Federal Reserve would need to consider the impact of sudden or disorderly changes and would need to pursue policies consistent with financial stability and established principles of entering and exiting priced services. Therefore, the Board will not require the Fedwire Services to develop recovery or orderly wind-down plans under principle 3.

In order to foster competition with private-sector FMIs, however, the Board will require the Federal Reserve priced services to hold six months of the Fedwire Funds Service's current operating expenses as liquid financial assets and equity on the pro forma balance sheet used in determining Reserve Bank fees for priced services.^{11 12} This balance sheet is used for imputing costs in the private-sector adjustment factor used to establish Fedwire Funds Service fees.¹³ If it is

¹¹ As required by the Monetary Control Act of 1980, the Board has historically required and will continue to require that the Fedwire Services be operated and priced in a manner that fosters competition, improves the efficiency of the payment mechanism, and lowers costs of these services to society. The Board established a set of pricing principles that governs the schedule of fees for the Federal Reserve priced services, including the Fedwire Services, that is consistent with these objectives. (12 U.S.C. 248a(c)(3); http://www.federalreserve.gov/paymentsystems/pfs_principles.htm).

¹² Consistent with the PFMI, the calculation of these current operating expenses would exclude depreciation and amortization expenses.

¹³ Federal Reserve priced services fees are set to recover, over the long run, all direct and indirect costs and imputed costs, including financing costs, taxes, and certain other expenses, as well as the return on equity (profit) that would have been earned if a private business provided the services. The imputed costs and imputed profit are collectively referred to as the private-sector adjustment factor. The Board's current method for calculating the private-sector adjustment factor involves developing an estimated Federal Reserve priced services pro forma balance sheet using actual

necessary to impute additional assets or equity, the incremental cost will be incorporated into the pricing of Fedwire Funds Service fees. In applying the PSR policy, the Board will monitor the implementation of Regulation HH and the final policy for issues of consistency and competitive equity between private-sector systems and the Fedwire Funds Service.

Expectations for certain FMIs that are part of a larger legal entity. An FMI may be one of several business lines of a larger legal entity. As a single legal entity, the firm's equity supports all of the business lines, but the Board's expectations under principle 15 may only apply to one of those business lines. In the proposal, the Board asked whether there are any reasonable methodologies for determining which of the liquid financial assets and equity held at the legal entity level belong to a particular business line. One commenter suggested that separate pro forma balance sheets could be created for a particular business line. After consideration of the comment, the Board believes it may not be useful for certain FMIs to attribute assets and equity to a business line on separate pro forma statements because it may not be possible to ring-fence assets within a legal entity in insolvency. Therefore, consistent with the approach described above for the Fedwire Funds Service and the approach in the final rule for Regulation HH, the Board would allow an FMI to use the assets and equity held at the legal entity level to meet the relevant requirements in principle 15.

J. Tiered Participation Arrangements

Proposed principle 19 stated that an FMI should identify, monitor, and manage the material risks to the FMI arising from tiered participation arrangements. These arrangements are those in which firms that are not members in the FMI (indirect participants) rely on the services provided by members of the FMI (direct participants) to access the FMI's payment, clearing, and settlement facilities. The Board received two comment letters that addressed this proposed principle.

Applicability of the proposed principle. A commenter stated that the Board did not adequately articulate the

risk that tiered participation arrangements pose and opposed the principle because it does not believe that it or its participants bear any significant risk from its participants' relationships with their customers. After consideration of the comment and analysis, the Board continues to believe that for certain FMIs, based on the design of their settlement arrangements, material risks could arise from tiered participation arrangements that are borne by the FMI, including by its participants. For example, in an FMI in which a direct participant processes large transaction values on behalf of a large customer such as a large correspondent bank, the failure of the customer could jeopardize the direct participant's ability to meet its obligations to the FMI or to the other participants in the FMI, potentially resulting in liquidity dislocations.

Tiered participation arrangements could also pose other risks to the FMI, including operational risk. For example, an FMI may need to understand how its direct participants manage any spikes in volume submitted to the FMI on behalf of indirect participants. Understanding the potential for spikes in volume will allow the FMI to prepare to have the scalable operational capacity necessary to process those volumes effectively, such that it is able to achieve its service-level objectives.

Therefore, the Board believes that material risks to an FMI, including to its participants, may arise from tiered participation arrangements. The Board expects FMIs to seek to understand the risks associated with the relationships between direct participants and their customers in order to be able to assess whether any material risk to the FMI, including to its other participants, exists. The Board recognizes, however, that certain FMIs, including their participants, may not bear any material risks from these arrangements due to the design of their settlement arrangements or due to the characteristics of the markets they serve. These FMIs should conduct an analysis to support their conclusion.

Expectations for an FMI with respect to tiered participation arrangements. One commenter stated that it is unclear what would actually be expected of an FMI under the proposed principle. The commenter stated that the Board should make clear that it does not expect an FMI that does not bear any risk from its participants or their customers to take any action with respect to principle 19.

The Board expects that an FMI will conduct an analysis to determine whether any material risks arise from tiered participation arrangements that

are borne by the FMI, including by its participants as a result of their participation in the FMI. Depending on the nature of their payment, clearing, settlement, or recording activities, FMIs' methodologies for conducting the analysis may differ. For example, some FMIs may choose to gather information about the volume and value of activity processed by direct participants on behalf of indirect participants in the FMI or other relevant information. Where such information would be useful, an FMI may consider defining reasonable thresholds and other factors for gathering the information in order to minimize burden. If the FMI determines that no material risks exist to the FMI, including to its participants, from tiered participation arrangements, the Board would not expect the FMI to take any further action. If material risks are identified, the Board would expect the FMI to take steps to mitigate or manage these risks. The Board does not expect, however, an FMI to manage risks that arise between a direct participant and its customers, but rather only to manage the material risks to the FMI, including to its other participants.

The Board expects that an FMI will review and update its analysis of risks arising from tiered participation arrangements at the earlier of every two years or following material changes to the system design or operations or the environment in which the FMI operates if those changes could affect its analysis. If an FMI's review of its analysis indicates that the FMI faces no material risks from tiered participation arrangements, then no further action would be required.

Duplicative monitoring. One commenter stated that an expectation that an FMI will monitor the risks posed by indirect participants would be costly and duplicative of monitoring activities of regulators and the direct participants in the FMI. After consideration of the comment, the Board continues to believe that monitoring by direct participants or by their supervisors may not fully address all risks that may arise from tiered participation arrangements. Direct participants would likely monitor risks posed to them by their customers but may not consider how their actions to mitigate or manage those risks could affect the FMI, including its other participants. In addition, the supervisory focus for certain direct participants is typically different from that for FMIs, and supervisory monitoring of direct participants also might not take into account the effects of tiered participation arrangements on the FMI, including its other participants. Direct participants in an

priced services assets and liabilities. The remaining components on the balance sheet, such as equity, are imputed as if these services were provided by a publicly traded firm. The capital structure of imputed equity is derived from the market for publicly traded firms, subject to minimum equity constraints consistent with those required by the Federal Deposit Insurance Corporation for a well-capitalized institution.

FMI may also be subject to varying degrees of supervision. Therefore, the onus should be on the FMI to understand the tiered participation arrangements in the system and the impact of these relationships on the FMI, including on its participants.

Scope of the principle. One commenter stated that the Board should expect FMIs to consider material risks arising from tiered participation arrangements only where the indirect participants are known by the FMI, have an agreement binding them to the FMI's rules, or may have a direct connection to the FMI. The Board believes that material risks can originate from arrangements with a range of indirect participants having a range of relationships or arrangements with the FMI. If such arrangements may pose material risks, the FMI should seek to gather information from its direct participants on those arrangements and assess the risks from those arrangements. Therefore, the Board will expect an FMI to understand generally the arrangements between its direct participants and firms that access the services of the FMI through the direct participants, whether or not these firms are bound by some part of the rules or have a direct connection to the FMI.¹⁴ The FMI, however, should focus its analysis on the direct customers of the direct participants and need not extend its analysis to other tiers of customers, such as the customers of the customers of the direct participants.

Conflicts of interest and antitrust issues. One commenter stated that proposed principle 19 raises conflicts of interest and antitrust issues. The commenter stated that collecting data on indirect participation would give the board of directors of the FMI a complete picture of each participant's relationships with its most important customers, which could create a conflict of interest if the FMI's board of directors is made up of representatives of the member banks. The commenter also stated that the proposed principle appeared to require FMIs to encourage indirect participants that are large relative to their direct participants to move to a larger direct participant or become direct participants themselves, which could create antitrust issues if the FMI's actions to meet the principle

appear to third parties as an effort by the FMI to favor its owner banks.

The Board believes that conflicts of interest or antitrust issues that may arise from expectations with respect to principle 19 can be avoided through the careful design of the information-gathering and risk-management processes developed by the FMI. First, the FMI's board of directors does not have to see a complete picture of each participant's relationships with its customers. The FMI can put controls in place that would minimize potential conflicts to ensure that information is shared in an appropriate manner that would allow the board of directors to carry out its responsibility for the comprehensive management of risks. Second, the Board does not necessarily expect an FMI to encourage indirect participants that are large relative to their direct participants to move to a larger direct participant or become direct participants themselves. The FMI may choose other methods for mitigating or managing risks arising from tiered participation arrangements. For example, if the FMI is concerned that a direct participant's exposures to its indirect participants could cause it to default to the FMI, the FMI may require the direct participant to provide additional collateral to mitigate the relevant financial risks posed by its relationships with its customers.

The Board has adopted the text of this principle as proposed.

K. Efficiency and Effectiveness

Proposed principle 21 stated that an FMI should be efficient and effective in meeting the requirements of its participants and the markets it serves. One commenter stated that an FMI that does not meet the requirements of its participants and the market it serves or that does not meet its objectives efficiently will not survive in the market. The commenter suggested that the Board remove the principle or redefine efficiency and effectiveness in terms of market judgments.¹⁵

The Board continues to believe that the expectation for an FMI to be efficient and effective should be included in the policy and that the terms efficiency and effectiveness should not be defined solely in terms of market judgments. The Board agrees with the comment that market forces

may encourage an FMI to be efficient and effective, particularly in cases where it has a direct competitor. Many markets for payment, clearing, and settlement services, however, are monopolies or oligopolies. Furthermore, it may be difficult for market participants to determine if a particular FMI is efficient and effective due to imperfect information about the FMI. Therefore, market judgments alone may be insufficient to encourage the FMI to operate efficiently and effectively. The Board has adopted the text of this principle as proposed.

L. Transparency

Proposed principle 23 stated that an FMI should publicly disclose all relevant rules and key procedures. Consistent with the principle, section I.B.2 of the proposed policy sets forth the Board's expectation that FMIs subject to its supervisory authority complete the CPSS-IOSCO disclosure framework and make their disclosure readily available to the public.¹⁶ A commenter stated that certain procedures should not be publicly disclosed because they would help unauthorized persons gain access to the system.

The Board agrees that certain procedures should not be publicly disclosed in detail if such detail would undermine the FMI's safety and soundness. The Board stated in the proposed policy that, although disclosures should be robust, the Board does not expect FMIs to disclose to the public sensitive information that could expose system vulnerabilities or otherwise put the FMI at risk. For example, disclosing the detail included in the FMI's business continuity plan could expose the vulnerabilities of the system, and in this case it would be sufficient to disclose publicly only key highlights of the plan. The Board has adopted the text of the policy as proposed.

M. Compliance Dates

The Board proposed that the revised policy become effective upon publication of the final version in the **Federal Register**. The Board also noted that several of the expectations in the proposed policy were new or heightened and may require additional time to implement, such as up to six months after adoption of the policy. The Board noted that these expectations may include the revised expectations in section I.B.2 on transparency and the expectation to manage risks arising in

¹⁴ For example, some firms may submit transactions or instructions to an FMI directly under the account of a direct participant. In this case, the firm may be bound by the FMI's rules, but the direct participant would be accountable for the firm's performance on its obligations. In other FMIs, indirect participants are not bound by the rules of the FMI and do not have a direct connection to the FMI.

¹⁵ In the NPRM for Regulation HH, the Board explained that efficiency generally encompasses what a designated FMU chooses to do, how it does it, and the resources required by the designated FMU to perform its functions. Effectiveness refers to whether the designated FMU is meeting its goals and objectives, which include the requirements of its participants and the markets it serves.

¹⁶ Designated FMUs are subject to Regulation HH (§ 234.3(a)(23)(iv)) rather than this policy.

tiered participation arrangements under principle 19. New or heightened expectations also included the establishment of plans for recovery and orderly wind-down as necessary to meet the expectations under principle 3; the establishment of rules and procedures that explicitly address uncovered credit losses and liquidity shortfalls as necessary to meet the expectations under principles 4 and 7, respectively; and the maintenance of sufficient liquid net assets funded by equity and a viable plan for raising additional equity as necessary to meet the expectations under principle 15. In the proposal, the Board asked whether there are any other expectations that may require additional time to implement and whether six months is sufficient to implement the changes necessary to meet the expectations.

The Board received three comment letters that addressed the compliance date for the new or heightened expectations proposed in the revised policy. One commenter agreed with the six-month extension. Two commenters stated that a longer extension may be necessary, and one of these suggested that a minimum of 18 months be allowed to meet the expectations in the proposed policy, especially if the expectations under principle 19 on tiered participation arrangements are finalized as proposed.

After consideration of the comments and analysis, the Board is adopting an overall effective date for the PSR policy revisions of December 31, 2014. However, the Board will begin to apply the new or heightened risk-management and transparency expectations as of December 31, 2015. The Board believes that this additional time may be necessary to allow FMIs time to complete their processes and procedures for changes to their rulebooks and to minimize burden on FMIs and the markets they serve. FMIs, however, are encouraged to meet the expectations in the PSR policy as soon as possible.

One commenter also stated that the expectations under proposed principle 20 on links may require additional time to implement because implementation will require extensive cooperation and coordination between FMIs. These expectations, however, are included in the existing PSR policy and are not new or heightened.¹⁷ Therefore, the Board will retain its expectation that FMIs subject to the policy meet principle 20

on the effective date of the final revised PSR policy.

III. Administrative Law Matters

A. Competitive Impact Analysis

The Board has established procedures for assessing the competitive impact of rule or policy changes that have a substantial impact on payment system participants.¹⁸ Under these procedures, the Board will assess whether a change would have a direct and material adverse effect on the ability of other service providers to compete effectively with the Federal Reserve in providing similar services due to differing legal powers or constraints, or due to a dominant market position of the Federal Reserve deriving from such differences. If no reasonable modifications would mitigate the adverse competitive effects, the Board will determine whether the anticipated benefits are significant enough to proceed with the change despite the adverse effects.

This final policy sets forth revised risk-management standards, which are based on the PFMI, for certain FMIs, including the Federal Reserve Bank-operated Fedwire Services. In a separate, related **Federal Register** notice, the Board amended its Regulation HH risk-management standards, which apply to certain designated FMUs as required by Title VIII of the Dodd-Frank Act, based on the PFMI. At least one currently designated FMU that is subject to Regulation HH (The Clearing House Payments Company, L.L.C., with respect to its operation of the Clearing House Interbank Payments System (CHIPS)) competes with the Fedwire Funds Service. One commenter expressed concern that differences in language between the risk-management standards in Regulation HH and in part I of the PSR policy may result in two different sets of risk-management standards for FMUs. The commenter also stated that the Board should ensure that the requirements for designated FMUs in Regulation HH with respect to general business risk in § 234.3(a)(15) should also be imposed on the equivalent Reserve Bank service.

The final revisions to the risk-management and transparency expectations in part I of the PSR policy are consistent with those in final Regulation HH. As discussed above, a different level of detail is required for Regulation HH as compared to part I of the PSR policy. Regulation HH is an

enforceable rule applicable to designated FMUs other than those supervised by the CFTC or SEC, so additional details from the key considerations and explanatory notes of the PFMI were incorporated in the rule text to provide greater clarity on the Board's expectations. The PSR policy, on the other hand, is a policy statement that provides guidance with respect to the Board's exercise of its other supervisory or regulatory authority over other financial market infrastructures (including those operated by the Federal Reserve Banks) or their participants, its participation in cooperative oversight arrangements for financial market infrastructures, or the provision of intraday credit to eligible Federal Reserve account holders. Incorporating the headline standards from the PFMI is consistent with the purpose of the document and the Board's long-standing principles-based approach to its PSR policy. The Board will be guided by the key considerations and the explanatory text of the PFMI, as well as its interpretation of the corresponding provisions of Regulation HH, in its application of the PSR policy. The Board does not intend for differences in language in the two documents to lead to inconsistent requirements for Reserve Bank-operated FMIs and their private sector competitors.

The Board recognizes the critical role that the Fedwire Services play in the financial system and is committed to applying risk-management standards to the Reserve Banks' Fedwire Funds Service that are at least as stringent as the applicable Regulation HH standards applied to designated FMUs that provide similar services. The final revisions to part I of the PSR policy provide that the treatment of Reserve Bank systems will be consistent with that of private-sector systems in order to avoid any material adverse effect on the ability of other service providers to compete effectively with the Reserve Banks.

There are, however, several risk-management standards for which flexibility in implementation will be necessary for the Fedwire Services given the Federal Reserve's legal framework and structure and its roles as monetary authority and liquidity provider.¹⁹ The Board does not expect that the difference in approach to implementing

¹⁷ See sections I.C.2.a.xix and I.C.2.b.xi of the existing policy.

¹⁸ These procedures are described in the Board's policy statement "The Federal Reserve in the Payments System," as revised in March 1990 (55 FR 11648 (Mar. 29, 1990)).

¹⁹ These standards include principle 2 on governance, principle 3 on the framework for the comprehensive management of risks, principle 4 on credit risk, principle 5 on collateral, principle 7 on liquidity risk, principle 13 on participant-default rules and procedures, principle 15 on general business risk, and principle 18 on access and participation requirements.

these standards for the Fedwire Funds Service as compared to the requirements for CHIPS would create a significant difference in operating costs for the two entities, with the possible exception of the expectation to hold unencumbered liquid financial assets and equity under principle 15. In order to foster competition with private-sector systems, the Board will incorporate the cost of this requirement into the pricing of the Fedwire Funds Service. As discussed above, although the Fedwire Funds Service does not face the risk that a business shock would cause the service to wind down in a disorderly manner and disrupt the stability of the financial system, in order to foster competition with private-sector systems, the Board will require the Fedwire Funds Service to impute the cost of maintaining liquid assets and equity to cover general business losses, similar to the requirement for designated FMUs in § 234.3(a)(15)(i). The Board will also monitor the implementation of the final policy for issues of consistency and competitive equity between private-sector systems and the Fedwire Funds Service. Therefore, the Board believes the policy will have no material adverse effect on the ability of other service providers to compete effectively with the Reserve Banks.

B. Paperwork Reduction Act Analysis

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506; 5 CFR part 1320, Appendix A.1), the Board reviewed the final policy under the authority delegated to the Board by the Office of Management and Budget. For purposes of calculating burden under the Paperwork Reduction Act, a “collection of information” involves 10 or more respondents. Any collection of information addressed to all or a substantial majority of an industry is presumed to involve 10 or more respondents (5 CFR 1320.3(c), 1320.3(c)(4)(ii)). The Board estimates there are fewer than 10 respondents, and these respondents do not represent all or a substantial majority of payment, clearing, and settlement systems. Therefore, no collections of information pursuant to the Paperwork Reduction Act are contained in the final policy.

IV. Federal Reserve Policy On Payment System Risk

Introduction

Risks In Payment, Clearing, Settlement, and Recording Systems

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- Part II. Federal Reserve Intraday Credit Policies
- Appendix—CPSS—IOSCO Principles for Financial Market Infrastructures

Introduction

Financial market infrastructures (FMIs) are critical components of the nation's financial system. FMIs are multilateral systems among participating financial institutions, including the system operator, used for the purposes of clearing, settling, or recording payments, securities, derivatives, or other financial transactions.^{1 2} FMIs include payment

systems, central securities depositories, securities settlement systems, central counterparties, and trade repositories. The safety and efficiency of these systems may affect the safety and soundness of U.S. financial institutions and, in many cases, are vital to the financial stability of the United States. Given the importance of FMIs, the Board of Governors of the Federal Reserve System (Board) has developed this policy to set out the Board's views, and related standards, regarding the management of risks that FMIs present to the financial system and to the Federal Reserve Banks (Reserve Banks). In adopting this policy, the Board's objective is to foster the safety and efficiency of payment, clearing, settlement, and recording systems and to promote financial stability, more broadly.

Part I of this policy sets out the Board's views, and related standards, regarding the management of risks in FMIs, including those operated by the Reserve Banks. In setting out its views, the Board seeks to encourage FMIs and their primary regulators to take the standards in this policy into consideration in the design, operation, monitoring, and assessment of these systems. The Board will be guided by this part, in conjunction with relevant laws, regulations, and other Federal Reserve policies, when exercising its supervisory and regulatory authority over FMIs or their participants, providing accounts and services to FMIs, participating in cooperative oversight and similar arrangements for FMIs with other authorities, or providing intraday credit to eligible Federal Reserve account holders. Designated financial market utilities subject to the Board's Regulation HH are not subject to the risk-management or transparency expectations set out in this policy.³

² The term “financial institution,” as used in this policy, refers to a broad array of organizations that engage in financial activity, including depository institutions, securities dealers, and futures commission merchants.

³ The term “financial market utility” is defined in Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) as “any person that manages or operates a multilateral system for the purpose of transferring, clearing, or settling payments, securities, or other financial transactions among financial institutions or between financial institutions and the person.” Trade repositories, which the Dodd-Frank Act defines as providing “facilities for comparison of data respecting the terms of settlement of securities or futures transactions,” are not included in the term “financial market utility” (12 U.S.C. 5462). Financial market utilities are, therefore, a subset of the broader set of entities defined as FMIs. Under Title VIII, the Financial Stability Oversight Council designates certain financial market utilities as

Continued

Part II of this policy governs the provision of intraday credit or “daylight overdrafts” in accounts at the Reserve Banks and sets out the general methods used by the Reserve Banks to control their intraday credit exposures.⁴ Under this part, the Board recognizes that the Federal Reserve has an important role in providing intraday balances and credit to foster the smooth operation of the payment system. The Reserve Banks provide intraday balances by way of supplying temporary, intraday credit to healthy depository institutions, predominantly through collateralized intraday overdrafts.⁵ The Board believes that such a strategy enhances intraday liquidity while controlling risk to the Reserve Banks by providing incentives to collateralize daylight overdrafts. The Board also aims to limit the burden of the policy on healthy depository institutions that use small amounts of intraday credit.

Through this policy, the Board expects financial system participants, including private-sector FMI and the Reserve Banks, to reduce and control settlement and other systemic risks arising in FMIs, consistent with the smooth operation of the financial system. This policy is also designed to govern the provision of intraday balances and credit while controlling the Reserve Banks’ risk by (1) making financial system participants and FMIs aware of the types of basic risks that may arise in the payment, clearing, settlement, or recording process; (2) setting explicit risk-management expectations; (3) promoting appropriate transparency by FMIs to help inform participants and the public; and (4) establishing the policy conditions governing the provision of Federal Reserve intraday credit to eligible account holders. The Board’s adoption

systemically important. The Board’s Regulation HH is discussed in section I.B.1.b below.

⁴ To assist depository institutions in implementing part II of this policy, the Board has prepared two documents, the *Overview of the Federal Reserve’s Payment System Risk Policy* (Overview) and the *Guide to the Federal Reserve’s Payment System Risk Policy* (Guide), which are available at http://www.federalreserve.gov/paymentsystems/psr_relolicies.htm. The Overview summarizes the Board’s policy on the provision of intraday credit, including net debit caps and daylight overdraft fees, and is intended for use by institutions that incur only small amounts of daylight overdrafts. The Guide explains in detail how these policies apply to different institutions and includes procedures for completing a self-assessment and filing a cap resolution, as well as information on other aspects of the policy.

⁵ The term “depository institution,” as used in this policy, refers not only to institutions defined as depository institutions in 12 U.S.C. 461(b)(1)(A), but also to U.S. branches and agencies of foreign banking organizations, Edge and agreement corporations, trust companies, and bankers’ banks, unless the context indicates a different reading.

of this policy in no way diminishes the primary responsibilities of financial system participants to address the risks that may arise through their operation of or participation in FMIs.

Risks in Payment, Clearing, Settlement, and Recording Systems

The basic risks in payment, clearing, settlement, and recording systems may include credit risk, liquidity risk, operational risk, and legal risk. In the context of this policy, these risks are defined as follows:⁶

- **Credit risk:** The risk that a counterparty, whether a participant or other entity, will be unable to meet fully its financial obligations when due, or at any time in the future.

- **Liquidity risk:** The risk that a counterparty, whether a participant or other entity, will be unable to meet fully its financial obligations when due, although it may be able to do so in the future. An FMI, through its design or operation, may bear or generate liquidity risk in one or more currencies in its payment or settlement process.⁷ In this context, liquidity risk may arise between or among the system operator and the participants in the FMI, the system operator and other entities (such as settlement banks, nostro agents, or liquidity providers), the participants in the FMI and other entities, or two or more participants in the FMI.

- **Operational risk:** The risk that deficiencies in information systems or internal processes, human errors, management failures, or disruptions from external events will result in the reduction, deterioration, or breakdown of services provided by the FMI.⁸

- **Legal risk:** The risk of loss from the unexpected or uncertain application of a law or regulation.

These risks also arise between financial institutions as they clear, settle, and record payments and other financial transactions and must be managed by institutions, both individually and collectively.⁹

⁶ The definitions of credit risk, liquidity risk, operational risk, and legal risk are consistent with those presented in the PFMI.

⁷ Deliveries of currency are payments, and FMIs that conduct such activity should consider these deliveries to be payments in the management of liquidity risk.

⁸ Operational risk also includes physical threats, such as natural disasters and terrorist attacks, and information security threats, such as cyberattacks. Further, deficiencies in information systems or internal processes include errors or delays in processing, system outages, insufficient capacity, fraud, data loss, and leakage.

⁹ Several existing regulatory and bank supervision guidelines and policies also are directed at financial institutions’ management of the risks posed by interbank payment and settlement activity. For example, the Board’s Regulation F (12 CFR part

Further, FMIs may increase, shift, concentrate, or otherwise transform risks in unanticipated ways. FMIs, for example, may pose systemic risk to the financial system because the inability of one or more of its participants to perform as expected may cause other participants to be unable to meet their obligations when due. The failure of one or more of an FMI’s participants to settle their payments or other financial transactions as expected, in turn, could create credit or liquidity problems for participants and their customers, the system operator, other financial institutions, and the financial markets the FMI serves. Thus, such a failure might lead ultimately to a disruption in the financial markets more broadly and undermine public confidence in the nation’s financial system.

Mitigating the risks that arise in FMIs is especially important because of the interdependencies such systems inherently create among financial institutions. In many cases, interdependencies are a normal part of an FMI’s structure or operations. Although they can facilitate the safety and efficiency of the FMI’s payment, clearing, settlement, or recording processes, interdependencies can also present an important source or transmission channel of systemic risk. Disruptions can originate from any of the interdependent entities, including the system operator, the participants in the FMI, and other systems, and can spread quickly and widely across markets if the risks that arise among these parties are not adequately measured, monitored, and managed. For example, interdependencies often create complex and time-sensitive transaction and payment flows that, in combination with an FMI’s design, can lead to significant demands for intraday credit or liquidity, on either a regular or an extraordinary basis.

The Board recognizes that the Reserve Banks, as settlement institutions, have an important role in providing intraday balances and credit to foster the smooth operation and timely completion of money settlement processes among financial institutions and between financial institutions and FMIs. To the extent that the Reserve Banks are the source of intraday credit, they may face a risk of loss if such intraday credit is not repaid as planned. In addition, measures taken by Reserve Banks to limit their intraday credit exposures

206) directs insured depository institutions to establish policies and procedures to avoid excessive exposures to any other depository institution, including exposures that may be generated through the clearing and settlement of payments.

may shift some or all of the associated risks to financial institutions and FMIs.

In addition, mitigating the risks that arise in certain FMIs is critical to the areas of monetary policy and banking supervision. The effective implementation of monetary policy, for example, depends on both the orderly settlement of open market operations and the efficient movement of funds throughout the financial system via the financial markets and the FMIs that support those markets. Likewise, supervisory objectives regarding the safety and soundness of financial institutions must take into account the risks FMIs, both in the United States and abroad, pose to financial institutions that participate directly or indirectly in, or provide settlement, custody, or credit services to, such systems.

Part I. Risk Management for Financial Market Infrastructures

This part sets out the Board's views, and related standards, regarding the management of risks in FMIs, including those operated by the Reserve Banks. The Board will be guided by this part, in conjunction with relevant laws, regulations, and other Federal Reserve policies, when exercising its authority in (1) supervising the Reserve Banks under the Federal Reserve Act; (2) supervising state member banks, Edge and agreement corporations, and bank holding companies, including the exercise of authority under the Bank Service Company Act, where applicable; (3) carrying out certain of its responsibilities under Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act); (4) setting or reviewing the terms and conditions for the use of Reserve Bank accounts and services; and (5) developing and applying policies for the provision of intraday liquidity to eligible Reserve Bank account holders. This part will also guide the Board, as appropriate, in its interactions and cooperative efforts with other domestic and foreign authorities that have responsibilities for regulating, supervising, or overseeing FMIs within the scope of this part. The Board's adoption of this policy is not intended to exert or create supervisory or regulatory authority over any particular class of institutions or arrangements where the Board does not have such authority.

A. Scope

FMIs within the scope of part I include public- and private-sector payment systems that expect to settle a daily aggregate gross value of U.S.

dollar-denominated transactions exceeding \$5 billion on any day during the next 12 months.^{10 11} FMIs within the scope of this part also include central securities depositories, securities settlement systems, central counterparties, and trade repositories irrespective of the value or nature of the transactions processed by the system.¹² These FMIs may be organized, located, or operated within the United States (domestic systems), outside the United States (offshore systems), or both (cross-border systems) and may involve currencies other than the U.S. dollar (non-U.S. dollar systems and multi-currency systems).¹³ The scope of the policy also includes any payment system based or operated in the United States that engages in the settlement of non-U.S. dollar transactions if that payment system would be otherwise subject to the policy.¹⁴

Part I does not apply to market infrastructures such as trading exchanges, trade-execution facilities, or multilateral trade-compression systems. This part is also not intended to apply to bilateral payment, clearing, or settlement relationships, where an FMI is not involved, between financial institutions and their customers, such as traditional correspondent banking and government securities clearing services. The Board believes that these market infrastructures and relationships do not constitute FMIs for purposes of this policy and that risk-management issues

¹⁰ A "payment system" is a set of instruments, procedures, and rules for the transfer of funds between or among participants. Payment systems include, but are not limited to, large-value funds transfer systems, automated clearinghouse systems, check clearinghouses, and credit and debit card settlement systems. The scope of this policy also includes payment-versus-payment settlement systems for foreign exchange transactions.

¹¹ In determining whether it is included in the scope of this policy, a payment system should look at its projected "next" twelve-month period. "Aggregate gross value of U.S. dollar-denominated transactions" refers to the total dollar value of individual U.S. dollar transactions settled in the payment system, which also represents the sum of total U.S. dollar debits (or credits) to all participants before or in absence of any netting of transactions.

¹² A "central securities depository" is an entity that provides securities accounts and central safekeeping services. A "securities settlement system" is an entity that enables securities to be transferred and settled by book entry and allows transfers of securities free of or against payment. A "central counterparty" is an entity that interposes itself between counterparties to contracts traded in one or more financial markets, becoming the buyer to every seller and the seller to every buyer. A "trade repository" is an entity that maintains a centralized electronic record of transaction data. These definitions are based on those in the PFMI.

¹³ Non-U.S. dollar systems may be of interest to the Board if they are used by U.S. financial institutions or may have the ability to affect financial stability, more broadly.

¹⁴ The daily gross value threshold will be calculated on a U.S. dollar equivalent basis.

associated with these market infrastructures and relationships are more appropriately addressed through other relevant supervisory and regulatory processes.

B. Policy Expectations for Certain Financial Market Infrastructures

This section sets out the Board's views, and related standards, with respect to risk-management and transparency for the subset of FMIs described below in section B.1, including the Reserve Banks' Fedwire Funds Service and Fedwire Securities Service (collectively, Fedwire Services). The Board believes these FMIs should have comprehensive risk management as well as a high degree of transparency.

1. Risk Management

Authorities, including central banks, have promoted sound risk-management practices by developing internationally accepted minimum standards that promote the safety and efficiency of FMIs. Specifically, the Committee on Payment and Settlement Systems (CPSS) and Technical Committee of the International Organization of Securities Commissions (IOSCO) report on *Principles for Financial Market Infrastructures* (PFMI) establishes minimum standards for payment systems that are systemically important, central securities depositories, securities settlement systems, central counterparties, and trade repositories for addressing areas such as legal risk, governance, credit and liquidity risks, general business risk, operational risk, and other types of risk.¹⁵ The PFMI reflects broad market input and has been widely recognized, supported, and endorsed by U.S. authorities, including the Federal Reserve, U.S. Securities and Exchange Commission (SEC), and U.S. Commodity Futures Trading Commission (CFTC). These standards are also part of the Financial Stability Board's (FSB's) Key Standards for Sound Financial Systems.¹⁶

The Board believes that the implementation of the PFMI by the FMIs within the scope of this section will help promote their safety and

¹⁵ In addition to these risk-management standards, the PFMI sets out responsibilities for authorities for FMIs, including central banks, in order to provide for effective regulation, supervision, and oversight of FMIs.

¹⁶ The FSB's Key Standards for Sound Financial Systems are available at http://www.financialstabilityboard.org/cos/key_standards.htm. The FSB is an international forum that was established to develop and promote the implementation of effective regulatory, supervisory and other financial sector policies. The FSB includes the U.S. Department of the Treasury, the Board, and the SEC.

efficiency in the financial system and foster greater financial stability in the domestic and global economy. Accordingly, the Board has incorporated into the PSR policy principles 1 through 24 from the PFMI, as set forth in the appendix.¹⁷ In applying part I of this policy, the Board will be guided by the key considerations and explanatory notes from the PFMI as well as its interpretation of the corresponding provisions of Regulation HH.¹⁸

a. Fedwire Services

The Board recognizes the critical role the Reserve Banks' Fedwire Services play in the financial system and requires them to meet or exceed the standards set forth in the appendix to this policy, consistent with the guidance on central bank-operated systems provided in the PFMI and with the requirements in the Monetary Control Act.¹⁹

b. Designated Financial Market Utilities for Which the Board is the Supervisory Agency Under Title VIII of the Dodd-Frank Act

The Board's Regulation HH imposes risk-management standards applicable to a designated financial market utility for which the Board is the Supervisory Agency.²⁰ The risk-management standards in Regulation HH are based

on the PFMI. As required under Title VIII of the Dodd-Frank Act, the risk-management standards seek to promote robust risk management, promote safety and soundness, reduce systemic risks, and support the stability of the broader financial system. Designated financial market utilities for which the Board is the Supervisory Agency are required to comply with the risk-management standards in Regulation HH and are not subject to the standards in the appendix.

c. Other Financial Market Infrastructures That are Subject to the Board's Supervisory Authority Under the Federal Reserve Act

The Board expects all other FMIs that are subject to its supervisory authority under the Federal Reserve Act, including FMIs that are members of the Federal Reserve System, to meet or exceed the risk-management standards in the appendix.

d. All Other Central Securities Depositories, Securities Settlement Systems, Central Counterparties, and Trade Repositories

The Board encourages all other central securities depositories, securities settlement systems, central counterparties, and trade repositories, whether they are located within or outside the United States, to meet or exceed the risk-management standards in the appendix to this policy. Where the Board does not have authority over a central securities depository, securities settlement system, central counterparty, or trade repository, the Board will be guided by this policy in its cooperative efforts with other FMI authorities.

e. Other Systemically Important Offshore and Cross-Border Payment Systems

The Board encourages systemically important offshore and cross-border payment systems that are not included in any of the categories above to meet or exceed the risk-management standards in the appendix to this policy.²¹ The Board will be guided by this policy in its cooperative efforts with other payment system authorities.

2. Transparency

Transparency helps ensure that relevant information is provided to an FMI's participants, authorities, and the public to inform sound decisionmaking, improve risk management, enable market discipline, and foster confidence in markets more broadly. In particular,

public disclosures play a critical role in allowing current and prospective participants, as well as other stakeholders, to understand an FMI's operations and the risks associated with using its services and to manage more effectively their risks with respect to the FMI. The Board believes that FMIs are well-positioned to provide the information necessary to support greater market transparency and to maintain financial stability.

The Board expects an FMI that is subject to its supervisory authority, but not subject to Regulation HH, to disclose to its participants information about the risks and costs that they incur by participating in the FMI, consistent with the requirements in principle 23 in the appendix.²² At a minimum, the FMI should disclose to its participants overviews of the FMI's system design and operations, rules and key procedures, key highlights of business continuity arrangements, fees and other material costs, aggregate transaction volumes and values, levels of financial resources that can be used to cover participant defaults, and other information that would facilitate its participants' understanding of the FMI and its operations and their evaluation of the risks associated with using that FMI.

In addition, the Board expects such an FMI to complete the disclosure framework set forth in the CPSS-IOSCO *Principles for Financial Market Infrastructures: Disclosure Framework and Assessment Methodology* ("disclosure framework" and "assessment methodology").²³ The disclosure framework establishes the international baseline set of information that all FMIs are expected to disclose publicly and review regularly.²⁴ An FMI is encouraged to use the guiding questions in the assessment methodology to guide the content and level of detail in their disclosures. The Board expects each FMI to make its disclosure readily available to the public, such as by posting it on the FMI's public Web site, to achieve maximum transparency.

To ensure each FMI's accountability for the accuracy and completeness of its disclosure, the Board expects the FMI's

¹⁷ The Board's Regulation HH contains risk-management standards that are based on the PFMI for certain designated financial market utilities. Regulation HH (12 CFR part 234) is available at <http://www.federalreserve.gov/bankinfo/reg/reglisting.htm#HH>.

¹⁸ The Board will also look to the CPSS-IOSCO *Principles for Financial Market Infrastructures: Disclosure Framework and Assessment Methodology*, which is available at <http://www.bis.org/cpmi/publ/d106.pdf>, and other related documents.

¹⁹ Certain standards may require flexibility in the way they are applied to central bank-operated systems because of central banks' unique role in the financial markets and their public responsibilities. These principles include principle 2 on governance, principle 3 on the framework for the comprehensive management of risks, principle 4 on credit risk, principle 5 on collateral, principle 7 on liquidity risk, principle 13 on participant-default rules and procedures, principle 15 on general business risk, and principle 18 on access and participation requirements. For instance, the Reserve Banks should refer to part II of this policy for managing their credit risk arising from the provision of intraday credit to users of the Fedwire Services.

²⁰ The term "Supervisory Agency" is defined in Title VIII as the "Federal agency that has primary jurisdiction over a designated financial market utility under Federal banking, securities, or commodity futures laws" (12 U.S.C. 5462(8)). Under Title VIII, the Board must prescribe risk-management standards for designated financial market utilities for which the Board or another Federal banking agency is the appropriate Supervisory Agency (12 U.S.C. 5464(a)). There are currently no designated financial market utilities for which another federal banking agency is the Supervisory Agency.

²¹ These systems may be used by U.S. financial institutions, clear or settle U.S. dollars, or have the ability to affect financial stability, more broadly.

²² The Board's Regulation HH imposes an equivalent public disclosure requirement.

²³ See CPSS-IOSCO, *Principles for Financial Market Infrastructures: Disclosure Framework and Assessment Methodology*, December 2012, available at <http://www.bis.org/cpmi/publ/d106.pdf>.

²⁴ Although the Board expects disclosures to be robust, it does not expect FMIs to disclose to the public sensitive information that could expose system vulnerabilities or otherwise put the FMI at risk (for example, specific business continuity plans).

senior management and board of directors to review and approve each disclosure upon completion. Further, in order for an FMI's disclosure to reflect its current rules, procedures, and operations, the Board expects the FMI to update the relevant parts of its disclosure following changes to the FMI or the environment in which it operates, which would significantly change the accuracy of the statements in its disclosure. At a minimum, the FMI is expected to review and update as warranted its disclosure every two years.

As part of its ongoing oversight of FMIs, the Board will review public disclosures by FMIs subject to its supervisory authority to ensure that the Board's policy objectives and expectations are being met.²⁵ Where necessary, the Board will provide feedback to the FMIs regarding the content of these disclosures and their effectiveness in achieving the policy objectives discussed above.²⁶ The Board acknowledges that FMIs vary in terms of the scope of instruments they settle and markets they serve. It also recognizes that FMIs may operate under different legal and regulatory constraints, charters, and corporate structures. The Board will consider these factors when reviewing the disclosures and in evaluating how an FMI addresses a particular standard. Where the Board does not have statutory or exclusive authority over an FMI, it will be guided by this policy in cooperative efforts with other domestic or foreign authorities to promote comprehensive disclosures by FMIs as a means to achieve greater safety and efficiency in the financial system.

C. General Policy Expectations for Other Payment Systems Within the Scope of the Policy

The Board encourages payment systems within the scope of this policy, but that are not included in any of the categories in section B above, to implement a general risk-management framework appropriate for the risks the payment system poses to the system operator, system participants, and other

relevant parties as well as the financial system more broadly.

1. Establishment of a Risk-Management Framework

A risk-management framework is the set of objectives, policies, arrangements, procedures, and resources that a system employs to limit and manage risk.

Although there are a number of ways to structure a sound risk-management framework, all frameworks should

- a. identify risks clearly and set sound risk-management objectives;
- b. establish sound governance arrangements to oversee the risk-management framework;
- c. establish clear and appropriate rules and procedures to carry out the risk-management objectives; and
- d. employ the resources necessary to achieve the system's risk-management objectives and implement effectively its rules and procedures.

a. Identify Risks Clearly and Set Sound Risk-Management Objectives

The first element of a sound risk-management framework is the clear identification of all risks that have the potential to arise in or result from the system's settlement process and the development of clear and transparent objectives regarding the system's tolerance for and management of such risks. System operators should identify the forms of risk present in their system's settlement process as well as the parties posing and bearing each risk. In particular, system operators should identify the risks posed to and borne by them, the system participants, and other key parties such as a system's settlement banks, custody banks, and third-party service providers. System operators should also analyze whether risks might be imposed on other external parties and the financial system more broadly.

In addition, system operators should analyze how risk is transformed or concentrated by the settlement process. System operators should also consider the possibility that attempts to limit one type of risk could lead to an increase in another type of risk. Moreover, system operators should be aware of risks that might be unique to certain instruments, participants, or market practices. Where payment systems have inter-relationships with or dependencies on other FMIs, system operators should also analyze whether and to what extent any cross-system risks exist and who bears them.

Using their clear identification of risks, system operators should establish the risk tolerance of the system, including the levels of risk exposure that are acceptable to the system

operator, system participants, and other relevant parties. System operators should then set risk-management objectives that clearly allocate acceptable risks among the relevant parties and set out strategies to manage this risk. Risk-management objectives should be consistent with the objectives of this policy, the system's business purposes, and the type of payment instruments and markets for which the system clears and settles. Risk-management objectives should also be communicated to and understood by both the system operator's staff and system participants.

System operators should reevaluate their risks in conjunction with any major changes in the settlement process or operations, the transactions settled, the system's rules or procedures, or the relevant legal and market environments. System operators should review the risk-management objectives regularly to ensure that they are appropriate for the risks posed by the system, continue to be aligned with the system's purposes, remain consistent with this policy, and are being effectively adhered to by the system operator and participants.

b. Establish Sound Governance Arrangements To Oversee the Risk-Management Framework

Systems should have sound governance arrangements to implement and oversee their risk-management frameworks. The responsibility for sound governance rests with a system operator's board of directors or similar body and with the system operator's senior management. Governance structures and processes should be transparent; enable the establishment of clear risk-management objectives; set and enforce clear lines of responsibility and accountability for achieving these objectives; ensure that there is appropriate oversight of the risk-management process; and enable the effective use of information reported by the system operator's management, internal auditors, and external auditors to monitor the performance of the risk-management process.²⁷ Individuals responsible for governance should be qualified for their positions, understand their responsibilities, and understand their system's risk-management framework. Governance arrangements should also ensure that risk-management information is shared in forms, and at times, that allow

²⁵ Any review of a disclosure by the Board should not be viewed as an approval or guarantee of the accuracy of an FMI's disclosure. Without the express approval of the Board, an FMI may not state that its disclosure has been reviewed, endorsed, approved, or otherwise not objected to by the Board.

²⁶ If the Board materially disagrees with the content of an FMI's disclosure, it will communicate its concerns to the FMI's senior management and possibly to its board of directors, as appropriate. The Board may also discuss its concerns with other relevant authorities, as appropriate.

²⁷ The risk-management and internal audit functions should also be independent of those responsible for day-to-day functions.

individuals responsible for governance to fulfill their duties effectively.

c. Establish Clear and Appropriate Rules and Procedures To Carry out the Risk-Management Objectives

Systems should have rules and procedures that are appropriate and sufficient to carry out the system's risk-management objectives and that are consistent with its legal framework. Such rules and procedures should specify the respective responsibilities of the system operator, system participants, and other relevant parties. Rules and procedures should establish the key features of a system's settlement and risk-management design and specify clear and transparent crisis management procedures and settlement failure procedures, if applicable.²⁸

d. Employ the Resources Necessary To Achieve the System's Risk-Management Objectives and Implement Effectively its Rules and Procedures

System operators should ensure that the appropriate resources and processes are in place to allow the system to achieve its risk-management objectives and implement effectively its rules and procedures. In particular, the system operator's staff should have the appropriate skills, information, and tools to apply the system's rules and procedures and achieve the system's risk-management objectives. System operators should also ensure that their facilities and contingency arrangements, including any information system resources, are sufficient to meet their risk-management objectives.

2. Other Considerations for a Risk-Management Framework

Payment systems differ widely in form, function, scale, and scope of activities, and these characteristics result in differing combinations and levels of risks. Thus, the exact features of a system's risk-management framework should be tailored to the risks of that system. The specific features of a risk-management framework may entail tradeoffs between efficiency and risk reduction, and payment systems will need to consider these tradeoffs when designing appropriate rules and procedures. In considering such tradeoffs, however, it is critically important that system

operators take into account the costs and risks that may be imposed on all relevant parties, including parties with no direct role in the system. Furthermore, in light of rapidly evolving technologies and risk-management practices, the Board encourages all system operators to consider making risk-management improvements when cost-effective.

The Board may seek to understand how a system achieves the four elements of a sound risk-management framework set out above. In this context, the Board may seek to obtain information from system operators regarding their risk-management framework, risk-management objectives, rules and procedures, significant legal analyses, general risk analyses, analyses of the credit and liquidity effects of settlement disruptions, business continuity plans, crisis management procedures, and other relevant documentation.²⁹ The Board also may seek to obtain data or statistics on system activity on an ad hoc or ongoing basis. All information provided to the Federal Reserve for the purposes of this policy will be handled in accordance with all applicable Federal Reserve policies on information security, confidentiality, and conflicts of interest.

D. Cooperation With Other Authorities in Regulating, Supervising, and Overseeing Financial Market Infrastructures

When the Board does not have statutory or exclusive authority over an FMI covered by this policy, this section will guide the Board, as appropriate, in its interactions with other domestic and foreign authorities to promote effective risk management in and transparency by FMIs. For example, the Federal Reserve may have an interest in the safety and efficiency of FMIs outside the United States that are subject to regulation, supervision, or oversight by another authority but that provide services to financial institutions supervised by the Board or conduct activity that involves the U.S. dollar.³⁰ In its interactions with

other domestic and foreign authorities, the Board will encourage these authorities to adopt and to apply the internationally accepted principles set forth in the appendix when evaluating the risks posed by and to FMIs and individual system participants that these authorities regulate, supervise, or oversee.

In working with other authorities, the Board will seek to establish arrangements for effective and practical cooperation that promote sound risk-management outcomes. The Board believes that cooperative arrangements among relevant authorities can be an effective mechanism for, among other things, (1) sharing relevant information concerning the policies, procedures, and operations of an FMI; (2) sharing supervisory views regarding an FMI; (3) discussing and promoting the application of robust risk-management standards; and (4) serving as a forum for effective communication, coordination, and consultation during normal circumstances, as well as periods of market stress.

When establishing such cooperative arrangements, the Board will be guided, as appropriate, by international principles on cooperative arrangements for the regulation, supervision, and oversight of FMIs. In particular, responsibility E in the PFMI addresses domestic and international cooperation among central banks, market regulators, and other relevant authorities and provides guidance to these entities for supporting each other in fulfilling their respective mandates with respect to FMIs. The CPSS report on *Central Bank Oversight of Payment and Settlement Systems* also provides important guidance on international cooperation among central banks.³¹ The Board believes this international guidance provides important frameworks for cooperating and coordinating with other authorities to address risks in domestic, cross-border, multi-currency, and, where appropriate, offshore FMIs.

Part II. Federal Reserve Intraday Credit Policies

[No change to existing part II of the policy.]

Appendix—CPSS-IOSCO Principles for Financial Market Infrastructures

Principle 1: Legal basis

An FMI should have a well-founded, clear, transparent, and enforceable legal

²⁸ Examples of key features that might be specified in a system's rules and procedures are controls to limit participant-based risks, such as membership criteria based on participants' financial and operational health; limits on credit exposures; and the procedures and resources to liquidate collateral. Other examples of key features might be business continuity requirements and loss-allocation procedures.

²⁹ To facilitate analysis of settlement disruptions, systems may need to develop the capability to simulate credit and liquidity effects on participants and on the system resulting from one or more participant defaults, or other possible sources of settlement disruption. Such simulations may need to include, if appropriate, the effects of changes in market prices, volatilities, or other factors.

³⁰ An FMI may be subject to supervision or oversight by the Board and other authorities, as a result of its legal framework, operating structure (for example, multi-currency or cross-border systems), or participant base. In such cases, the Board will be sensitive to the potential for duplicative or conflicting requirements, oversight gaps, or unnecessary costs and burdens imposed on the FMI.

³¹ See *Central Bank Oversight of Payment and Settlement Systems*, part B on "Principles for international cooperative oversight," May 2005, available at <http://www.bis.org/cpmi/publ/d68.pdf>.

basis for each material aspect of its activities in all relevant jurisdictions.

Principle 2: Governance

An FMI should have governance arrangements that are clear and transparent, promote the safety and efficiency of the FMI, and support the stability of the broader financial system, other relevant public interest considerations, and the objectives of relevant stakeholders.

Principle 3: Framework for the Comprehensive Management of Risks

An FMI should have a sound risk-management framework for comprehensively managing legal, credit, liquidity, operational, and other risks.

Principle 4: Credit Risk

An FMI should effectively measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes. An FMI should maintain sufficient financial resources to cover its credit exposure to each participant fully with a high degree of confidence. In addition, a central counterparty that is involved in activities with a more-complex risk profile or that is systemically important in multiple jurisdictions should maintain additional financial resources sufficient to cover a wide range of potential stress scenarios that should include, but not be limited to, the default of the two participants and their affiliates that would potentially cause the largest aggregate credit exposure to the central counterparty in extreme but plausible market conditions. All other central counterparties should maintain additional financial resources sufficient to cover a wide range of potential stress scenarios that should include, but not be limited to, the default of the participant and its affiliates that would potentially cause the largest aggregate credit exposure to the central counterparty in extreme but plausible market conditions.

Principle 5: Collateral

An FMI that requires collateral to manage its or its participants' credit exposure should accept collateral with low credit, liquidity, and market risks. An FMI should also set and enforce appropriately conservative haircuts and concentration limits.

Principle 6: Margin

A central counterparty should cover its credit exposures to its participants for all products through an effective margin system that is risk-based and regularly reviewed.

Principle 7: Liquidity Risk

An FMI should effectively measure, monitor, and manage its liquidity risk. An FMI should maintain sufficient liquid resources in all relevant currencies to effect same-day and, where appropriate, intraday and multiday settlement of payment obligations with a high degree of confidence under a wide range of potential stress scenarios that should include, but not be limited to, the default of the participant and its affiliates that would generate the largest aggregate liquidity obligation for the FMI in extreme but plausible market conditions.

Principle 8: Settlement Finality

An FMI should provide clear and certain final settlement, at a minimum by the end of the value date. Where necessary or preferable, an FMI should provide final settlement intraday or in real time.

Principle 9: Money Settlements

An FMI should conduct its money settlements in central bank money where practical and available. If central bank money is not used, an FMI should minimize and strictly control the credit and liquidity risk arising from the use of commercial bank money.

Principle 10: Physical Deliveries

An FMI should clearly state its obligations with respect to the delivery of physical instruments or commodities and should identify, monitor, and manage the risks associated with such physical deliveries.

Principle 11: Central Securities Depositories

A central securities depository should have appropriate rules and procedures to help ensure the integrity of securities issues and minimize and manage the risks associated with the safekeeping and transfer of securities. A central securities depository should maintain securities in an immobilized or dematerialized form for their transfer by book entry.

Principle 12: Exchange-of-Value Settlement Systems

If an FMI settles transactions that involve the settlement of two linked obligations (for example, securities or foreign exchange transactions), it should eliminate principal risk by conditioning the final settlement of one obligation upon the final settlement of the other.

Principle 13: Participant-Default Rules and Procedures

An FMI should have effective and clearly defined rules and procedures to manage a participant default. These rules and procedures should be designed to ensure that the FMI can take timely action to contain losses and liquidity pressures and continue to meet its obligations.

Principle 14: Segregation and Portability

A central counterparty should have rules and procedures that enable the segregation and portability of positions of a participant's customers and the collateral provided to the central counterparty with respect to those positions.

Principle 15: General Business Risk

An FMI should identify, monitor, and manage its general business risk and hold sufficient liquid net assets funded by equity to cover potential general business losses so that it can continue operations and services as a going concern if those losses materialize. Further, liquid net assets should at all times be sufficient to ensure a recovery or orderly wind-down of critical operations and services.

Principle 16: Custody and Investment Risks

An FMI should safeguard its own and its participants' assets and minimize the risk of loss on and delay in access to these assets. An FMI's investments should be in instruments with minimal credit, market, and liquidity risks.

Principle 17: Operational Risk

An FMI should identify the plausible sources of operational risk, both internal and external, and mitigate their impact through the use of appropriate systems, policies, procedures, and controls. Systems should be designed to ensure a high degree of security and operational reliability and should have adequate, scalable capacity. Business continuity management should aim for timely recovery of operations and fulfilment of the FMI's obligations, including in the event of a wide-scale or major disruption.

Principle 18: Access and Participation Requirements

An FMI should have objective, risk-based, and publicly disclosed criteria for participation, which permit fair and open access.

Principle 19: Tiered Participation Arrangements

An FMI should identify, monitor, and manage the material risks to the FMI

arising from tiered participation arrangements.

Principle 20: FMI Links

An FMI that establishes a link with one or more FMIs should identify, monitor, and manage link-related risks.

Principle 21: Efficiency and Effectiveness

An FMI should be efficient and effective in meeting the requirements of its participants and the markets it serves.

Principle 22: Communication Procedures and Standards

An FMI should use, or at a minimum accommodate, relevant internationally accepted communication procedures and standards in order to facilitate efficient payment, clearing, settlement, and recording.

Principle 23: Disclosure of Rules, Key Procedures, and Market Data

An FMI should have clear and comprehensive rules and procedures and should provide sufficient information to enable participants to have an accurate understanding of the risks, fees, and other material costs they incur by participating in the FMI. All relevant rules and key procedures should be publicly disclosed.

Principle 24: Disclosure of Market Data by Trade Repositories

A trade repository should provide timely and accurate data to relevant authorities and the public in line with their respective needs.

By order of the Board of Governors of the Federal Reserve System, November 6, 2014.

Robert deV. Frierson,
Secretary of the Board.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

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Airworthiness Directives; Piper Aircraft, Inc.

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are superseding Airworthiness Directive (AD) 76-06-09 for certain Piper Aircraft, Inc. Model PA-31P airplanes. AD 76-06-09 required repetitive inspection of certain exhaust system parts with replacement of parts mating with the turbocharger, as necessary, and allowed installation of a certain tailpipe v-band coupling as terminating action. This new AD requires the use of new service information and expands the scope of the inspections of the turbocharger exhaust system. This AD was prompted by reports of exhaust system failures, new service information, and the tailpipe v-band coupling used for terminating action is obsolete. We are issuing this AD to correct the unsafe condition on these products.

DATES: This AD is effective December 18, 2014.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of December 18, 2014.

The Director of the Federal Register approved the incorporation by reference of certain other publications listed in this AD as of July 17, 2013 (78 FR 35110, June 12, 2013).

ADDRESSES: For service information identified in this AD, contact Piper Aircraft, Inc., 2926 Piper Drive, Vero Beach, Florida 32960; telephone: (772) 567-4361; fax: (772) 978-6573; Internet: www.piper.com/home/pages/Publications.cfm; or Lycoming Engines, 652 Oliver Street, Williamsport, Pennsylvania 17701; telephone: (570) 323-6181; Internet: <http://www.lycoming.textron.com/support/publications/index.html>; as applicable. You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2014-0437; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800-647-5527) is

Document Management Facility, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Gary Wechsler, Aerospace Engineer, Atlanta Aircraft Certification Office, FAA, 1701 Columbia Avenue, College Park, Georgia 30337; telephone: (404) 474-5575; fax: (404) 474-5606; email: gary.wechsler@faa.gov.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 76-06-09, Amendment 39-3325 (43 FR 50417, October 30, 1978), ("AD 76-06-09"). AD 76-06-09 applied to certain Piper Aircraft, Inc. Model PA-31P airplanes. The NPRM published in the **Federal Register** on July 9, 2014 (79 FR 38806). The NPRM was prompted by reports of exhaust system failure. The NPRM proposed to retain certain requirements of AD 76-06-09. The NPRM also proposed to require the use of the new service information and expand the scope of the inspections of the turbocharger exhaust system. We are issuing this AD to correct the unsafe condition on these products.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (79 FR 38806, July 9, 2014) or on the determination of the cost to the public.

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting this AD as proposed except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (79 FR 38806, July 9, 2014) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (79 FR 38806, July 9, 2014).

Costs of Compliance

We estimate that this AD affects 85 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Visual inspection	3 work-hours × \$85 per hour = \$255	Not applicable	\$255	\$21,675
Review of maintenance records.	.5 work-hour × \$85 per hour = \$42.50	Not applicable	42.50	3,612.50

We have no way of determining how much damage may be found on each airplane during the inspection. The scope of damage on the exhaust system could vary from airplane to airplane due to the manner and environments the

airplane may operate. We estimate the following costs to do any necessary modification, installation, and/or replacement that would be required based on the results of the inspection. We have no way of determining what

damage may be found or the number of airplanes that might need the modification, installation, and/or replacement:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Modification of the exhaust pipe slip joint	5 work-hours × \$85 per hour = \$425	\$2,841	\$3,266
Installation of the bracket and clamp assembly	5 work-hours × \$85 per hour = \$425	5,000	5,425
Replacement of v-band coupling	2 work-hours × \$85 per hour = \$170	780	950

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 76–06–09, Amendment 39–3325 (43 FR 50417, October 30, 1978), and adding the following new AD:

2014–23–03 Piper Aircraft, Inc.:

Amendment 39–18019; Docket No. FAA–2014–0437; Directorate Identifier 2012–CE–036–AD.

(a) Effective Date

This AD is effective December 18, 2014.

(b) Affected ADs

This AD supersedes AD 76–06–09, Amendment 39–3325 (43 FR 50417, October 30, 1978).

(c) Applicability

This AD applies to Piper Aircraft, Inc. Model PA–31P airplanes, serial numbers 31P–1 through 31P–80 and 31P–7300110 through 31P–7730012, that are certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 78, Engine Exhaust.

(e) Unsafe Condition

This AD was prompted by reports of exhaust system failures, new service information issued by the manufacturer, and the tailpipe v-band coupling used for terminating action is obsolete. We are issuing this AD to prevent the possibility of an in-flight powerplant fire due to an exhaust system failure.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Inspection of Exhaust System

(1) Within the next 60 hours time-in-service (TIS) after December 18, 2014 (the effective date of this AD) or within the next 6 months after December 18, 2014 (the effective date of this AD), whichever occurs first, and repetitively thereafter at intervals not to exceed 60 hours TIS or 6 months, whichever occurs first, inspect the parts as specified in table 1 of paragraph (g)(1) of this AD, if installed.

TABLE 1 OF PARAGRAPH (g)(1) OF THIS AD: INSPECTION FOR PIPER AND LYCOMING EXHAUST SYSTEM PARTS

Product/part nomenclature	Make	Model/part No.	With a light and mirror or other method capable of achieving an equivalent visual resolution, inspect for the following conditions
Airplane	Piper	PA-31P	Bulges, cracks, and exhaust leak stains. Bulges, cracks, and exhaust leak stains. Bulges, cracks, and exhaust leak stains. Bulges, cracks, and exhaust leak stains. Bulges, cracks, and exhaust leak stains. Bulges, cracks, and exhaust leak stains. Cracks and exhaust leak stains. Cracks and exhaust leak stains. Cracks, looseness, and distortion. Cracks, looseness, and distortion. Cracks, looseness, and distortion.
Engine	Lycoming	TIGO-541-E series	
Pipe, exhaust, right-rear	Lycoming	78012	
Pipe, exhaust, left-rear	Lycoming	78008	
Pipe, rear exhaust adapter	Lycoming	LW-13027	
Tail pipe assembly, upper	Piper	46323-05	
Tail pipe assembly, lower	Piper	48788-05	
V-band coupling	Lycoming	LW-12093-5	
V-band coupling	Piper	555-366 or 557-369	
Isolator (CA-3383-1)	Piper	467-442	
Bracket—isolator, upper	Piper	47014-02	
Bracket—isolator, lower	Piper	47013-02	

(2) If any damage is found in any inspection required in paragraph (g)(1) of this AD, before further flight, do the corrective actions, as applicable, in paragraphs (g)(2)(i) through (g)(2)(iv).

(i) Replace Piper v-band couplings exhibiting cracks and/or exhaust leak stains with airworthy parts following Piper Aircraft, Inc. Mandatory Service Bulletin No. 644E, dated May 9, 2012. Replace Lycoming v-band couplings exhibiting cracks and/or exhaust leak stains with airworthy parts following Lycoming Service Instruction No. 1238B, Revision B, dated January 6, 2010.

Note to paragraphs (g)(2)(i) and (h)(2)(iii): During replacement of v-band couplings, we recommend not opening the v-band coupling more than the MINIMUM diameter necessary to clear coupled flanges. It is recommended to replace any locknuts and/or mating couplings with airworthy parts when locknuts do not exhibit a prevailing torque when installed.

(ii) Replace Lycoming exhaust system parts exhibiting bulges, cracks, and/or exhaust leak stains with airworthy parts following Lycoming Service Instruction No. 1320, dated March 7, 1975; or Textron Lycoming Service Instruction No. 1391, dated October 5, 1979, as applicable.

(iii) Replace Piper tail pipe assembly parts exhibiting bulges, cracks, and/or exhaust leak stains with airworthy parts following Piper Aircraft, Inc. Mandatory Service Bulletin No. 644E, dated May 9, 2012.

(iv) Replace Piper isolators and brackets exhibiting cracks, looseness and/or distortion following Piper Aircraft Corporation Service Bulletin No. 462A, dated November 3, 1975; and Piper Aircraft, Inc. Mandatory Service Bulletin No. 492A, dated May 29, 2012.

(h) Exhaust System Modifications

(1) Within the next 100 hours TIS after December 18, 2014 (the effective date of this AD) or within the next 12 months after December 18, 2014 (the effective date of this AD), whichever occurs first, review the airplane maintenance records to positively identify whether the modifications described in paragraphs (h)(1)(i) through (h)(1)(iii) of this AD have been done.

(i) Exhaust pipe slip joint modification following Piper Aircraft, Inc. Mandatory Service Bulletin No. 492A, dated May 29,

2012; and Textron Lycoming Mandatory Service Bulletin No. 393C, dated November 26, 1976.

(ii) Installation of bracket and clamp assembly following Piper Kit No. 760-974 as specified in Piper Aircraft, Inc. Mandatory Service Bulletin No. 492A, dated May 29, 2012; or Piper Aircraft, Inc. Service Bulletin 462A, dated November 3, 1975.

(iii) Replacement of Piper v-band coupling, part number 556-053, with Piper v-band coupling, part number 557-369, following Piper Aircraft, Inc. Mandatory Service Bulletin No. 644E, dated May 9, 2012.

(2) If you cannot positively identify that the modifications described in paragraphs (h)(1)(i) through (h)(1)(iii) of this AD have been done, before further flight, you must do the modifications described in paragraphs (h)(2)(i) through (h)(2)(iii), as applicable.

(i) Exhaust pipe slip joint modification following Piper Aircraft, Inc. Mandatory Service Bulletin No. 492A, dated May 29, 2012, and Textron Lycoming Mandatory Service Bulletin SB 393C, dated November 26, 1976.

(ii) Installation of bracket and clamp assembly following Piper Kit No. 760-974 as specified in Piper Aircraft, Inc. Mandatory Service Bulletin No. 492A, dated May 29, 2012; or Piper Aircraft Corporation Service Bulletin 462A, dated November 3, 1975.

(iii) Replacement of Piper v-band coupling, part number 556-053, with Piper v-band coupling, part number 557-369, following Piper Aircraft, Inc. Mandatory Service Bulletin No. 644E, dated May 9, 2012.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Atlanta Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in the Related Information, paragraph (j)(1) of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager

of the local flight standards district office/certificate holding district office.

(j) Related Information

For more information about this AD, contact Gary Wechsler, Aerospace Engineer, Atlanta ACO, FAA, 1701 Columbia Avenue, College Park, Georgia 30337; telephone: (404) 474-5575; fax: (404) 474-5606; email: gary.wechsler@faa.gov.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(3) The following service information was approved for IBR on December 18, 2014.

(i) Piper Aircraft Corporation Service Bulletin No. 462A, dated November 3, 1975.

(ii) Piper Aircraft, Inc. Mandatory Service Bulletin No. 492A, dated May 29, 2012.

(iii) Textron Lycoming Mandatory Service Bulletin SB 393C, dated November 26, 1976.

(4) The following service information was approved for IBR on July 17, 2013 (78 FR 35110, June 12, 2013).

(i) Piper Aircraft, Inc. Mandatory Service Bulletin No. 644E, dated May 9, 2012.

(ii) Lycoming Service Instruction No. 1238B, Revision B, dated January 6, 2010.

(iii) Lycoming Service Instruction No. 1320, dated March 7, 1975.

(iv) Textron Lycoming Service Instruction No. 1391, dated October 5, 1979.

(5) For the service information identified in this AD, contact Piper Aircraft, Inc., 2926 Piper Drive, Vero Beach, Florida 32960; telephone: (772) 567-4361; fax: (772) 978-6573; Internet: www.piper.com/home/pages/Publications.cfm; or Lycoming Engines, 652 Oliver Street, Williamsport, Pennsylvania 17701; telephone: (570) 323-6181; Internet: <http://www.lycoming.textron.com/support/publications/index.html>; as applicable.

(6) You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

(7) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Kansas City, Missouri, on November 4, 2014.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014-26706 Filed 11-12-14; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2014-0594; Directorate Identifier 2014-CE-022-AD; Amendment 39-18005; AD 2014-22-01]

RIN 2120-AA64

Airworthiness Directives; PILATUS AIRCRAFT LTD. Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are superseding Airworthiness Directive (AD) 2012-26-16 for all PILATUS AIRCRAFT LTD. Models PC-12, PC-12/45, PC-12/47, and PC-12/47E airplanes. This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as a need to incorporate new revisions into the Limitations section, Chapter 4, of the FAA-approved maintenance program (e.g., maintenance manual). We are issuing this AD to require actions to address the unsafe condition on these products.

DATES: This AD is effective December 18, 2014.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the AD as of December 18, 2014.

ADDRESSES: You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2014-0594; or in person at the Docket Management Facility, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

For service information identified in this AD, contact PILATUS AIRCRAFT LTD., Customer Service Manager, CH-6371 STANS, Switzerland; telephone: +41 (0) 41 619 33 33; fax: +41 (0) 41 619 73 11; Internet: <http://www.pilatus-aircraft.com> or email: SupportPC12@pilatus-aircraft.com. You may view this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

FOR FURTHER INFORMATION CONTACT:

Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4059; fax: (816) 329-4090; email: doug.rudolph@faa.gov.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to add an AD that would apply to all PILATUS AIRCRAFT LTD. Models PC-12, PC-12/45, PC-12/47, and PC-12/47E airplanes. That NPRM was published in the **Federal Register** on August 18, 2014 (79 FR 48701), and proposed to supersede AD 2012-26-16, Amendment 39-17311 (78 FR 11572, February 19, 2013).

Since we issued AD 2012-26-16, Amendment 39-17311 (78 FR 11572, February 19, 2013), PILATUS AIRCRAFT LTD. has issued revisions to the Limitations section of the airplane maintenance manual to include repetitive inspections of the inboard flap drive arms for cracks.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued AD No. 2014-0170, dated July 17, 2014 (referred to after this as "the MCAI"), to correct an unsafe condition for the specified products. The MCAI states:

The maintenance instructions and airworthiness limitations applicable to the Structure and Components of PC-12 aeroplanes are specified in the Aircraft Maintenance Manual (AMM) under Chapter 4, Airworthiness Limitation Section (ALS).

The instructions contained in the ALS document have been identified as mandatory actions for continued airworthiness and failure to comply with these instructions and limitations could potentially lead to an unsafe condition.

Pilatus Aircraft Ltd. recently issued Pilatus PC-12 AMM report 02049 issue 28 for PC-12, PC-12/45 and PC-12/47 aeroplanes and PC-12 AMM report 02300 issue 11 for PC-12/47E aeroplanes to incorporate new repetitive inspection intervals of the inboard

flap drive arms because of the detection of cracked parts.

For the reason described above, this AD retains the requirements of EASA AD 2013-0031, which is superseded, and requires implementation of the new maintenance requirements and/or airworthiness limitations.

The MCAI can be found in the AD docket on the Internet at: <http://www.regulations.gov/#!documentDetail;D=FAA-2014-0594-0003>.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the proposal and the FAA's response to each comment.

Request To Remove Actions Retained From AD 2012-26-16, Amendment 39-17311 (78 FR 11572, February 19, 2013) ("AD 2012-26-16")

Johan Kruger, Pilatus Aircraft Ltd., requested that we remove the actions retained from AD 2012-26-16, paragraphs (f)(1) and (f)(2) of the proposed AD from the final rule AD action. These actions were originally in AD 2009-14-13, Amendment 39-15963 (74 FR 34213, July 15, 2009), which was superseded by AD 2012-26-16.

Johan Kruger stated that the need to retain the actions previously required in AD 2012-26-16, paragraphs (f)(1) and (f)(2) of the proposed AD, no longer exists for the following reasons:

- In AD 2012-26-16, the initial compliance time for replacing the nose landing gear (NLG) torque tubes part number (P/N) 532.50.12.047 on Models PC-12 and PC-12/45 airplanes is within the next 100 hours time-in-service (TIS) after August 19, 2009 (the effective date retained from AD 2009-14-13) or 1 year after August 19, 2009, whichever occurs first. Compliance with this requirement should have been completed by September 20, 2010. AD 2012-26-16 also prohibits installing any NLG torque tube P/N 532.50.12.047 as of March 26, 2013 (the effective date retained from AD 2012-26-16).

- Even if P/N 532.50.12.047 had not been replaced as required in AD 2012-26-16, the life limit for P/N 532.50.12.047 in the airworthiness limitations section (ALS) of the airplane maintenance manual (AMM) referenced in the proposed AD is deemed adequate to address the potential unsafe condition.

- Since August 19, 2009, the effective date of AD 2009-14-13, Pilatus has not provided any P/N 532.50.12.047 as spares to any owners/operators in the United States. Pilatus is implying that

after the issuance of AD 2009–14–13, NLG torque tube P/N 532.50.12.047 has not been installed as a spare on any affected Model PC–12 and PC–12/45 airplane in the United States.

Johan Kruger clarified that the unsafe condition caused by NLG torque tube P/N 532.50.12.047 that was addressed in AD 2012–26–16, which was a carryover from AD 2009–14–13, has sufficiently been addressed and is now covered by the ALS of the AMM that is referenced in the proposed AD, which is unchanged from AD 2012–26–16.

We agree with the commenter. We have changed the final rule AD action based on this comment and have removed paragraphs (f)(1) and (f)(2) as presented in the proposed AD from this final rule AD action. Any airplane that has not operated since the torque tube requirement was initiated through AD 2009–14–13 may apply for an alternative method of compliance.

Request To Remove the Effective Date Imposed in the Proposed AD

Johan Kruger, Pilatus Aircraft Ltd., and Gerard Terpstra requested that the effective date imposed in paragraph (f)(3) of the proposed AD be removed.

The commenters stated that it is out of the ordinary to have a compliance effective date imposed in a proposed AD. The commenters also pointed out that the effective date is before the comment close date.

We agree with the commenters that compliance effective dates are not normally put in a proposed AD. The September 22, 2014, effective date in paragraph (f)(3) of the proposed AD was a mistake. There will be no enforcement for that date in the final rule AD action and comments were still allowed through the comment close date of October 6, 2014, before final rule action was taken.

We changed the final rule AD action based on these comments.

Request To Withdraw the Proposed AD

Gerard Terpstra requested that the proposed AD be withdrawn because compliance with the new airworthiness limitations is already mandatory under federal regulations.

Gerard Terpstra stated that Title 14 of the Code of Federal Regulations (CFR), part 23, Appendix G, makes the requirements in the ALS of the AMM mandatory and 14 CFR 91.403 additionally prohibits the operation of an airplane unless the requirements of the ALS of the AMM are complied with. Therefore, 14 CFR 39.5 cannot be the basis for issuing the proposed AD because no unsafe condition exists.

Gerard Terpstra also stated that by using 14 CFR part 39 here the FAA has in fact induced an unintended consequence of allowing an operator to delay the implementation of the new ALS requirements. For example, the FAA publishes an AD periodically to require compliance with the then “current” version of the ALS of the Pilatus PC–12 AMM, most recently with AD 2012–26–16, which became effective on March 26, 2013. Pilatus Aircraft Ltd. subsequently revised the ALS of the AMM by publishing two temporary revisions on March 13, 2014. Gerard Terpstra estimated the compliance date for the final rule AD action to be around the first week of November 2014 (if the FAA observes the 45-day comment period and the 35 days for complying with the AD after it becomes effective). Between the time that Pilatus Aircraft Ltd. published their temporary revision and the time the proposed AD becomes effective as a final rule AD action is approximately six months, thereby delaying compliance with the ALS by around six months.

Gerard Terpstra stated his understanding of the desire and requirement to have regulations harmonized between different countries and that is what is being done here. EASA issues an AD and the FAA follows suit and issues an AD. But in this instance the proposed AD is not required as the proper and appropriate Federal regulations are already in place to ensure that the ALS of the AMM are complied with.

We don't agree with the commenter. Based on guidance from the FAA's Office of the Chief Counsel (AGC), the definition of the word “current” is the ALS of the AMM that was delivered with the original airworthiness (A/W) certificate of each airplane. The only way the FAA can enforce the use of a newer version of the ALS to the AMM on the entire existing fleet is through 14 CFR part 39 AD action.

We agree that the new ALS to the AMM is binding for a new airplane upon the issuance of the A/W certificate or existing airplanes that have the requirement as part of their operational specifications (e.g., 14 CFR part 135 operations), but not for the entire existing fleet (e.g., 14 CFR part 91 operations). EASA is in agreement with the FAA and understands that the only way to require the most recent revision to the ALS section for existing fleets in either state of registry system is through AD action.

Conclusion

We reviewed the relevant data, considered the comments received, and

determined that air safety and the public interest require adopting the AD with the changes described previously and minor editorial changes. We have determined that these changes:

- Are consistent with the intent that was proposed in the NPRM (79 FR 48701, August 18, 2014) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (79 FR 48701, August 18, 2014).

We also determined that these changes will not increase the economic burden on any operator or increase the scope of the AD.

Costs of Compliance

We estimate that this AD will affect 770 products of U.S. registry. We also estimate that it will take about 16.5 work-hours per product to comply with the basic requirements of this AD. The average labor rate is \$85 per work-hour. Required parts will cost about \$300 per product. Based on these figures, we estimate the cost of this AD on U.S. operators to be \$1,310,925, or \$1,702.50 per product. This breaks down as follows:

- New inspections, etc. through incorporating maintenance manual limitations: 3.5 work-hours with parts about \$300 for a fleet cost of \$460,075, or \$597.50 per product.
- Wing main spar fastener holes inspection: 12 work-hours with no parts cost for fleet cost of \$785,400 or \$1,020 per product.
- Inboard flap drive arm inspection: 1 work-hour with no parts cost for fleet cost of \$65,450 or \$85 per product.

In addition, we estimate that any necessary corrective actions (on-condition costs) that must be taken based on the above inspections, etc. will take about 16 work-hours and require parts costing approximately \$10,000 for a cost of \$11,360 per product. We have no way of determining the number of products that may need these necessary corrective actions. This breaks down as follows:

- Replacements based on damaged parts or reduced life limits as a result of the new maintenance manual limitations: 6 work-hours with parts about \$4,000 for a cost of \$4,510 per product.
- Repairs to the wing spar as a result of the wing main spar fastener holes inspection: 7 work-hours with parts about \$5,000 for a cost of \$5,595 per product.
- Replacement of the inboard flap drive arm as a result of the inboard flap drive arm inspection: 3 work-hours with parts about \$1,000 for a cost of \$1,255.

The only costs that will be imposed by this AD over that already required by AD 2012–26–16 is the inboard flap arm inspection and replacement as necessary and the addition of 92 airplanes from 678 airplanes to 770 airplanes.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this AD:

- (1) Is not a "significant regulatory action" under Executive Order 12866,
- (2) Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),
- (3) Will not affect intrastate aviation in Alaska, and
- (4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2014–0594; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM, the regulatory

evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5527) is in the ADDRESSES section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by removing Amendment 39–17311 (78 FR 11572, February 19, 2013), and adding the following new AD:

2014–22–01 PILATUS AIRCRAFT LTD.:
Amendment 39–18005; Docket No. FAA–2014–0594; Directorate Identifier 2014–CE–022–AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective December 18, 2014.

(b) Affected ADs

This AD supersedes AD 2012–26–16, Amendment 39–17311 (78 FR 11572, February 19, 2013).

(c) Applicability

This AD applies to PILATUS AIRCRAFT LTD. Models PC–12, PC–12/45, PC–12/47, and PC–12/47E airplanes, all manufacturer serial numbers (MSNs), certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 5: Time Limits.

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as a need to incorporate new revisions into the Limitations section, Chapter 4, of the FAA-approved maintenance program (e.g., maintenance manual). The limitations were revised to include repetitive inspections of the inboard flap drive arms for crack(s). These actions are required to ensure the continued operational safety of the affected airplanes.

(f) Actions and Compliance

Unless already done, do the actions in paragraphs (f)(1) through (f)(5) of this AD:

(1) Before further flight after December 18, 2014 (the effective date of this AD), insert Data module code 12–A–04–00–00–00A–000A–A, "STRUCTURAL, COMPONENT AND MISCELLANEOUS—AIRWORTHINESS LIMITATIONS," dated March 13, 2014, of the Pilatus Model type—PC–12, PC–12/45, PC–12/47, Aircraft Maintenance Manual (AMM), Document No. 02049, 12–A–AM–00–00–00–I, revision 28, dated May 31, 2014, for Models PC–12, PC–12/45, PC–12/47, and Data module code 12–B–04–00–00–00A–000A–A, "STRUCTURAL AND COMPONENT LIMITATIONS—AIRWORTHINESS LIMITATIONS," dated March 13, 2014, of the Pilatus Model type—PC–12/47E MSN–1001–UP, Aircraft Maintenance Manual (AMM), Document No. 02300, 12–B–AM–00–00–00–I, revision 11, dated May 31, 2014, for Model PC–12/47E, into the Limitations section of the FAA-approved maintenance program (e.g., maintenance manual). These limitations section revisions do the following:

- (i) Establish an inspection of the inboard flap drive arms,
- (ii) Specify replacement of components before or upon reaching the applicable life limit, and
- (iii) Specify accomplishment of all applicable maintenance tasks within certain thresholds and intervals.

(2) Only authorized Pilatus Service Centers can do the Supplemental Structural Inspection Document (SSID) as required by the documents in paragraph (f)(1) of this AD because deviations from the type design in critical locations could make the airplane ineligible for this life extension.

(3) If no compliance time is specified in the documents listed in paragraph (f)(1) of this AD when doing any corrective actions where discrepancies are found as required in paragraph (f)(1)(iii) of this AD, do these corrective actions before further flight after doing the applicable maintenance task.

(4) During the accomplishment of the actions required in paragraphs (f)(1)(i), (f)(1)(ii), and (f)(1)(iii) of this AD, if a discrepancy is found that is not identified in the documents listed in paragraph (f)(1) of this AD, before further flight after finding the discrepancy, contact PILATUS AIRCRAFT LTD. at the address specified in paragraph (i) of this AD for a repair scheme and incorporate that repair scheme.

(5) Within the next 3 months after December 18, 2014 (the effective date of this AD) or within the next 150 hours TIS after December 18, 2014 (the effective date of this AD), whichever occurs first, inspect the inboard flap drive arms for cracks and take all necessary corrective actions.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to Doug Rudolph, Aerospace Engineer, FAA,

Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4059; fax: (816) 329-4090; email: doug.rudolph@faa.gov.

(i) Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(ii) AMOCs approved for AD 2012-26-16, Amendment 39-17311 (77 FR 11572, February 19, 2013) are not approved as AMOCs for this AD.

(2) **Airworthy Product:** For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(h) Special Flight Permit

Special flight permits are prohibited.

(i) Related Information

Refer to MCAI European Aviation Safety Agency (EASA) AD No. 2014-0170, dated July 17, 2014, for related information. The MCAI can be found in the AD docket on the Internet at: <http://www.regulations.gov/> #!documentDetail;D=FAA-2014-0594-0003.

(j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Data module code 12-A-04-00-00-00A-000A-A, "STRUCTURAL, COMPONENT AND MISCELLANEOUS—AIRWORTHINESS LIMITATIONS," dated March 13, 2014, of the Pilatus Model type—PC-12, PC-12/45, PC-12/47, Aircraft Maintenance Manual (AMM), Document No. 02049, 12-A-AM-00-00-00-I, revision 28, dated May 31, 2014.

(ii) Data module code 12-B-04-00-00-00A-000A-A, "STRUCTURAL AND COMPONENT LIMITATIONS—AIRWORTHINESS LIMITATIONS," dated March 13, 2014, of the Pilatus Model type—PC-12/47E MSN-1001-UP, Aircraft Maintenance Manual (AMM), Document No. 02300, 12-B-AM-00-00-00-I, revision 11, dated May 31, 2014.

Note to paragraph (j)(2) of this AD: Data module code 12-A-04-00-00-00A-000A-A, "STRUCTURAL, COMPONENT AND MISCELLANEOUS—AIRWORTHINESS LIMITATIONS," dated March 13, 2014, of the Pilatus Model type—PC-12, PC-12/45, PC-12/47, Aircraft Maintenance Manual (AMM), Document No. 02049, 12-A-AM-00-00-00-I, revision 28, dated May 31, 2014; and Data module code 12-B-04-00-00-00A-000A-A, "STRUCTURAL AND COMPONENT LIMITATIONS—AIRWORTHINESS LIMITATIONS," dated March 13, 2014, of the Pilatus Model type—

PC-12/47E MSN-1001-UP, Aircraft Maintenance Manual (AMM), Document No. 02300, 12-B-AM-00-00-00-I, revision 11, dated May 31, 2014, were issued as complete updates to the AMM Airworthiness Limitations sections.

(3) For Pilatus Aircraft LTD. service information identified in this AD, contact PILATUS AIRCRAFT LTD., Customer Service Manager, CH-6371 STANS, Switzerland; telephone: +41 (0) 41 619 33 33; fax: +41 (0) 41 619 73 11; Internet: <http://www.pilatus-aircraft.com> or email: SupportPC12@pilatus-aircraft.com.

(4) You may view this service information at FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Kansas City, Missouri, on October 20, 2014.

Derek Morgan,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014-26704 Filed 11-12-14; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 61 and 121

Pilot Age Limit Crew Pairing Requirement

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of policy.

SUMMARY: This document notifies the public of the Federal Aviation Administration's policy regarding enforcement of the pilot pairing requirement in the "Part 121 Pilot Age Limit" final rule. Currently, while the International Civil Aviation Organization (ICAO) standards allow a person between the age of 60 and 65 to serve as pilot in command (PIC) of an airplane with two or more pilots, in international commercial air transport operations, the PIC must be paired with a pilot younger than 60 years of age. Parts 61 and 121 of title 14, of the Code of Federal Regulations contain similar limitations. However, a recent amendment to the ICAO standards would remove this pilot pairing requirement. Instead, all pilots serving on airplanes in international commercial air transport operations with more than one pilot may serve

beyond 60 years of age (until age 65) without being paired with a pilot under 60 years of age. This ICAO amendment triggers the sunset of the statutory authority that provides the basis for the crew pairing limitations in title 14.

DATES: Effective November 13, 2014. If implementation by the International Civil Aviation Organization of Amendment 172 to Annex 1 is delayed, the FAA will publish notification of the date changes.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this document, contact Nancy Lauck Claussen, email: Nancy.L.Claussen@faa.gov; Air Transportation Division (AFS-200), Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267-8166. For legal questions concerning this document, contact Sara Mikolop, email: Sara.Mikolop@faa.gov; Office of Chief Counsel (AGC-200), Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267-3073.

SUPPLEMENTARY INFORMATION:

Fair Treatment of Experienced Pilots Act

On December 13, 2007, the Fair Treatment of Experienced Pilots Act (Pub. L. 110-135) amended title 49 of the United States Code by adding section 44729. Section 44729(a) raised the age limit for pilots serving in operations under part 121¹ from age 60 to age 65, subject to the limitations in section 44729(c) applicable to pilots in command on international flights.

Section 44729(c) specified a pilot pairing limitation for PICs serving on international flights. Specifically, section 44729(c)(1) provides, "A pilot who has attained 60 years of age may serve as pilot-in-command in covered operations between the United States and another country only if there is another pilot in the flight deck crew who has not yet attained 60 years of age." The pilot pairing requirement in section 44729(c)(1) is consistent with the pilot pairing standard in ICAO Annex 1 (Personnel Licensing), Chapter 2 (Licenses and Ratings for Pilots), Standard 2.1.10.

The crew pairing requirement in section 44729(c)(1) will sunset in accordance with section 44729(c)(2), on the date that ICAO removes the pilot pairing limitation in Standard 2.1.10. Section 44729(c)(2) states, "Paragraph

¹ The statute uses the term "covered operations" to describe part 121 operations. See 49 U.S.C. 44729(b).

[c](1), shall cease to be effective on such date as the Convention on International Civil Aviation provides that a pilot who has attained 60 years of age may serve as pilot-in-command in international commercial operations without regard to whether there is another pilot in the flight deck crew who has not attained age 60.”

During a meeting of the ICAO Council on March 3, 2014, Council members adopted Amendment 172 to Annex 1, Personnel Licensing. The amendment removes the requirement in Standard 2.1.10 to pair a pilot in command over age 60 with a pilot under age 60. Without the pairing requirement, all pilots on multi-pilot crews serving in international air transport commercial operations may continue to serve as long as they have not reached 65 years of age.² The Council anticipates implementation of Amendment 172 to Annex 1, Personnel Licensing, to be November 13, 2014.³ Accordingly, on November 13, 2014, the pilot pairing limitation in 49 U.S.C. 44729(c)(1) ceases to be effective.

“Part 121 Pilot Age Limit” Final Rule

On July 15, 2009, the Federal Aviation Administration (FAA) published the “Part 121 Pilot Age Limit” final rule (74 FR 34229) to conform FAA regulations to the statutory requirements in the Fair Treatment for Experienced Pilots Act (codified at 49 U.S.C. 44729). Based on the statutory authority in 49 U.S.C. 44729, the 2009 final rule raised the pilot age limitation from 60 to 65 and added the pilot pairing requirement for pilots conducting part 121 operations and other multi-pilot operations between or over the territory of more than one country using U.S. registered airplanes.⁴

In the final rule preamble, the agency stated that it believed that the Fair

Treatment for Experienced Pilots Act intended to harmonize FAA regulations with the ICAO standard pertaining to pilot age limitations and pilot pairing requirements, which would encompass international operations in addition to the part 121 operations identified by the Act. See 74 FR 34229, 34230 (July 15, 2009). The ICAO standard pertaining to pilot age limitations and pilot pairing applies to pilots serving in operations between his or her home state and another country as well as between two territories outside of his or her home state. Accordingly, to harmonize the agency’s regulations with the ICAO standard and further the intent of the Act, the 2009 final rule added the pilot age limitations and pilot pairing requirement for pilots conducting operations between two international territories using U.S. registered airplanes.⁵ As a result, for multi-pilot operations, the final rule increased the maximum age for a pilot to serve and added the pilot pairing requirement for part 121 operations and certain other international air service and air transportation operations using airplanes on the U.S. registry (14 CFR 121.383(d) and (e), 61.3(j) and 61.77(g)).

Effect of ICAO Amendment and Sunset of 49 U.S.C. 44729(c)(1) on Enforcement of FAA Regulations

As discussed previously, 49 U.S.C. 44729(c)(2) states that the pilot pairing requirement in 49 U.S.C. 44729(c)(1) ceases to be effective when ICAO amends its standard to remove the pilot pairing limitation. Once the pilot pairing limitation of 49 U.S.C. 44729(c)(1) ceases to be effective, the statutory basis for pilot pairing in §§ 121.383(d)(2), 121.383(e)(2), 61.3(j)(2) and 61.77(g) of title 14 of the Code of Federal Regulations will no longer exist

and those regulations will be contrary to 49 U.S.C. 44729. For this reason, beginning on the date the ICAO amendment is implemented, the FAA will no longer enforce the crew pairing requirements contained in 14 CFR 121.383(d)(2), 121.383(e)(2), 61.3(j)(2) and 61.77(g).

The FAA has initiated a rulemaking to conform applicable relevant regulations to the statute and anticipates publication of a final rule in 2015.⁶

Issued in Washington, DC, on November 5, 2014.

Reginald C. Govan,
Chief Counsel.

[FR Doc. 2014–26783 Filed 11–12–14; 8:45 am]

BILLING CODE 4910–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

14 CFR Part 1260

RIN 2700–AD79

Profit and Fee Under Federal Financial Assistance Awards

AGENCY: National Aeronautics and Space Administration.

ACTION: Final rule.

SUMMARY: NASA is revising the NASA Grant & Cooperative Agreement Handbook to clarify that NASA does not pay profit or fee on Federal Financial Assistance awards, i.e. grants and cooperative agreements, to non-profit organizations. This rule makes changes to NASA regulations to reflect that revision.

DATES: Effective December 15, 2014.

FOR FURTHER INFORMATION CONTACT: William Roets, NASA Office of Procurement, Contract Management Division, Suite 5K34, 202–358–4483, william.roets-1@nasa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

NASA published a proposed rule for Profit and Fee under Financial Assistance Awards in the **Federal Register** on January 11, 2012 (77 FR 1657). The public comment period closed on March 11, 2012. By the end of the established comment period, NASA received comments from one entity. However, those comments were subsequently determined to have been submitted to the incorrect docket and were not applicable to the proposed rule. After the specified end date for the

² Amendment 172 to Annex 1, Personnel Licensing, does not affect the maximum age permitted for pilots of engaged in single-pilot operations. Pilots serving in single-pilot operations must be below 60 years of age.

³ On March 25, 2014, ICAO notified the FAA that the date of implementation is anticipated to be November 13, 2014, to the extent the majority of ICAO contracting States have not registered their disapproval before July 14, 2014. On October 1, 2014, the FAA confirmed that ICAO has not amended the implementation date of November 13, 2014.

⁴ The 2009 final rule implemented the crew pairing requirements by amending part 121 as well as the regulations applicable to pilots with certificates issued under part 61, including a special purpose pilot authorization issued in accordance with § 61.77. As discussed in footnote 5, foreign air carrier operations and certain other operations conducted with U.S. registered aircraft solely outside of the U.S. must comply with ICAO standards in Annex 1 to the Convention on International Civil Aviation without further agency action.

⁵ The agency notes that in accordance with 14 CFR 129.5(b), “Each foreign air carrier conducting operations within the United States must conduct its operations in accordance with the Standards contained in Annex 1 (Personnel Licensing), Annex 6 (Operation of Aircraft), Part I (International Commercial Air Transport—Aeroplanes) or Part III (International Operations—Helicopters), as appropriate, and in Annex 8 (Airworthiness of Aircraft) to the Convention on International Civil Aviation.” Additionally, in accordance with 14 CFR 129.1(b), operations of U.S. registered aircraft solely outside of the U.S. in common carriage by a foreign person or a foreign air carrier must also be in compliance with the ICAO Standards identified in 14 CFR 129.5(b). Accordingly, for these operations, the ICAO amendment to the crew pairing limitation applies without further change to title 14 of the Code of Federal Regulations. The FAA further notes that beginning on the date of the ICAO amendment implementation, as an ICAO member state, no foreign air carrier conducting operations under part 129 may conduct operations to or from the United States with any pilot who has reached 65 years of age. This same limitation applies to operations covered by 14 CFR 129.1(b).

⁶ The FAA expects to make conforming changes to 14 CFR 61.3(j), 61.77(g) and 121.383(d)(2) and (e)(2).

submission of comments had passed, three organizations submitted late comments to the proposed rule. NASA accepted the late comments. Based on the comments received and subsequent revisions to the proposed rule, NASA published a second proposed rule in the **Federal Register** on February 25, 2014 (79 FR 10346). The public comment period closed on April 28, 2014. By the end of the established comment period, NASA received comments from three entities. After the specified end date for the submission of comments had passed, one organization submitted supplementary comments to their original comments. NASA accepted these late comments.

II. Discussion and Analysis

Historically, NASA has discouraged the payment of profit or fee under its Federal Financial Assistance awards because payment in excess of costs is inconsistent with the intent of grants and cooperative agreements which provide funding in the form of financial assistance to recipients for their performance of a public purpose. For commercial firms, payment of profit or fee is specifically prohibited under NASA grants and cooperative agreements (See NASA Grant and Cooperative Handbook, Subpart 1274.204). Because this prohibition does not include non-profit organizations, NASA's policy has been misinterpreted and inconsistent application has occurred.

Therefore, this final rule extends the prohibition on the payment of profit or fee to all recipients of NASA grants and cooperative agreements, alleviating the misinterpretation and inconsistent application of the policy.

Based on a review of the public comments discussed below, NASA has concluded that no change to the second proposed rule is necessary. NASA received comments from three respondents. New comments, not already addressed in response to the first proposed rule, are discussed below. Comments that were received in response to the first proposed rule were addressed in the second proposed rule at 79 FR 10346, February 25, 2014.

Comment 1: Respondent inquired if this rule impacts NASA Grant and Cooperative Handbook, Subpart 1274.204(f), profit applicability, which allows profit in some cases.

Response: This rule does not impact NASA Grant and Cooperative Handbook, Subpart 1274.204(f). Profit associated with cooperative agreements awarded to commercial firms may be paid by the recipient to subcontractors in accordance with Subpart 1274.204(f).

Comment 2: Respondent inquired as to whether profit or fee can be paid in the situation where a private consultant might be hired to help inform the effort. Private consultant's hourly rate could have profit or fee built into the rate and we may not have visibility into the components (direct and indirect costs, profit, etc. . . .) that comprise the hourly rate.

Response: This rule does not impact this situation. In this case, the hourly rate would invariably represent a commercial market rate for these services where a detailed cost breakdown of the hourly rate by cost element would not be required. Thus, profit or fee analysis would not be required.

Comment 3: Prohibiting the payment of profit or fee to non-profit organizations will have a devastating and large detrimental effect on non-profit organizations and their partners.

Response: NASA continues to support non-profit entities and the valuable contributions they supply to the NASA mission. NASA has historically discouraged the payment of profit or fee to non-profit entities. The intent of this rule is to clarify this point that NASA will not pay for profit or fee where profit or fee is defined as the amount above allowable costs. Management fees that are allowable costs within the guidelines established in OMB Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR Chapter I, Chapter II, Parts 200, 215, 220, 225, and 230) will continue to be paid.

Comment 4: Management fee is intended to provide a non-profit entity with a modest source of funds to meet business expenses that are not reimbursable. Non-profits have many costs that are not allowable under government regulations but must be paid by non-profit entities in order to keep operating. Without management fee, non-profits would find it impossible to continue operations.

Response: NASA pays for business expenses/costs that are reimbursable in accordance with the guidelines in OMB Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR Chapter I, Chapter II, Parts 200, 215, 220, 225, and 230). Paying business expenses/costs that are not reimbursable through a management fee would be circumventing these OMB guidelines, and inappropriate for financial assistance instruments.

Comment 5: Respondent stated that NASA's interpretation of statutory authorities was too narrowly focused

and that NASA has the statutory authority to pay a management fee to non-profit entities.

Response: NASA agrees that the Space Act of 1958 (42 U.S.C. 2473(c)(5)) provides NASA with broad authority and discretion to award grants and cooperative agreements to fulfill its mission. However, these authorities do not expressly or explicitly allow for the payment of profit or fee, sometimes referred to as a management fee, when such fee is defined as the amount above allowable costs. The payment of profit or fee under Federal Financial Assistance awards is inconsistent with the intent of grants and cooperative agreements which provide funding in the form of financial assistance to recipients for their performance of a public purpose and therefore should not be allowed.

Comment 6: Respondent took issue with the NASA statement that "Federal agencies are only authorized to pay for allowable, allocable, reasonable, and necessary costs" stating that there is no cost principle that requires that a cost must be "necessary" to the performance of a cooperative agreement.

Response: Pursuant to OMB Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, section 200.403, Factors affecting allowability of costs, "necessary" is part of the general criteria that a cost must meet in order to be allowable under Federal awards.

Comment 7: Respondent took issue with NASA statement that "grant and cooperative agreement regulation is incomplete in its coverage of profit and fee in that it fails to address non-profit organizations". Respondent stated that this statement is inaccurate. NASA Grant Information Circular (GIC) 99-1 is specific regulatory action regarding payment of management fees on grants and cooperative agreements to non-profit entities.

Response: NASA Grant Information Circulars (GICs) are non-regulatory, internal guidance and the grant and cooperative agreement regulation referred to was the NASA Grant and Cooperative Agreement Handbook which is codified beginning at 14 CFR part 1260.

Comment 8: Respondent stated that the final OMB Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR Chapter I, Chapter II, Parts 200, 215, 220, 225, and 230) rule provides NASA the authority to authorize fee or profit under an award. Specifically, the guidance states that "the non-Federal entity may not earn or keep any profit resulting from Federal financial

assistance, unless expressly authorized by the terms and conditions of the Federal award”.

Response: In implementing the OMB Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR Chapter I, Chapter II, Parts 200, 215, 220, 225, and 230), it is NASA policy to not pay profit or fee under grant and cooperative agreement awards. NASA maintains that it is inappropriate to pay profit and fee under its Federal Financial Assistance awards because payment in excess of costs is inconsistent with the intent of grant and cooperative agreements which provide funding in the form of financial assistance to recipients for their performance of a public purpose.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

NASA certifies that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, et seq., because the rule does not impose any additional requirements on small entities and currently less than 1 percent of recipients of NASA grants and cooperative agreements receive profit or management fees.

V. Paperwork Reduction Act

The Paper Reduction Act (Pub. L. 104–13) is not applicable because the prohibition on payment of profit and management fees by NASA does not require the submission of any information by recipients that requires the approval of the Office of Management and Budget under 44 U.S.C. 3501, et seq.

List of Subjects in 14 CFR 1260

Colleges and universities, Business and Industry, Grant programs, Grants administration, Cooperative agreements, State and local governments, Non-profit organizations, Commercial firms, Recipients.

Cynthia Boots,

Alternate Federal Register Liaison

Accordingly, 14 CFR Part 1260 is amended as follows:

PART 1260—GRANTS AND COOPERATIVE AGREEMENTS

- 1. The authority citation for 14 CFR 1260 continues to read as follows:

Authority: 42 U.S.C. 2473(c)(1), Pub. L. 97–258, 96 Stat. 1003 (31 U.S.C. 6301, et seq.), and OMB Circular A–110.

- 2. In § 1260.4, paragraph (b)(2) is revised to read as follows:

§ 1260.4 Applicability.

* * * * *

(b) * * *

(2) Payment of fee or profit is consistent with an activity whose principal purpose is the acquisition of goods and services for the direct benefit or use of the United States Government, rather than an activity whose principal purpose is assistance. Therefore, the grants officer shall use a procurement contract, rather than assistance instrument, in all cases where fee or profit is to be paid to the recipient of the instrument or the instrument is to be used to carry out a program where fee or profit is necessary to achieving program objectives. Grants and cooperative agreements shall not provide for the payment of fee or profit to the recipient.

* * * * *

- 3. In § 1260.10, paragraph (b)(1)(iv) is added to read as follows:

§ 1260.10 Proposals.

* * * * *

(b) * * *

(1) * * *

(iv) Payment of fee or profit is consistent with an activity whose principal purpose is the acquisition of goods and services for the direct benefit or use of the United States Government, rather than an activity whose principal purpose is assistance. Therefore, the grants officer shall use a procurement contract, rather than assistance instrument, in all cases where fee or profit is to be paid to the recipient of the instrument or the instrument is to be used to carry out a program where fee or profit is necessary to achieving program objectives. Grants and

cooperative agreements shall not provide for the payment of fee or profit to the recipient.

* * * * *

- 4. In § 1260.14, paragraph (e) is added to read as follows:

§ 1260.14 Limitations.

* * * * *

(e) Payment of fee or profit is consistent with an activity whose principal purpose is the acquisition of goods and services for the direct benefit or use of the United States Government, rather than an activity whose principal purpose is assistance. Therefore, the grants officer shall use a procurement contract, rather than assistance instrument, in all cases where fee or profit is to be paid to the recipient of the instrument or the instrument is to be used to carry out a program where fee or profit is necessary to achieving program objectives. Grants and cooperative agreements shall not provide for the payment of fee or profit to the recipient.

[FR Doc. 2014–26856 Filed 11–12–14; 8:45 am]

BILLING CODE 7510–13–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Docket No. SSA–2009–0038]

RIN 096–AH03

Revised Medical Criteria for Evaluating Genitourinary Disorders; Correction

AGENCY: Social Security Administration.

ACTION: Final rule; correction.

SUMMARY: This document corrects a misspelling in the regulatory language of our final rulemaking published in the **Federal Register** on Friday, October 10, 2014, titled Revised Medical Criteria for Evaluating Genitourinary Disorders.

DATES: Effective December 9, 2014.

FOR FURTHER INFORMATION CONTACT:

Cheryl A. Williams, Office of Medical Policy, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, (410) 965–1020. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213, or TTY 1–800–325–0778, or visit our Internet site, Social Security Online, at <http://www.socialsecurity.gov>.

SUPPLEMENTARY INFORMATION: On October 10, 2014 we published a final rulemaking in the **Federal Register** at 79 FR 61221. The final rulemaking contained an incorrect spelling of exstrophic. We are correcting that misspelling.

Correction

In final rule FR Doc 2014–24114 published on October 10, 2014 at 79 FR 61221, in the regulatory language section, make the following correction:

**Appendix 1 to Subpart P of Part 404—
[Corrected]**

■ 1. On page 61225 in the 2nd column, in paragraph A of Listing 106.00 of Part B of Appendix 1 to Subpart P of Part 404, correct “exotrophic” to read “exstrophic”.

Paul Kryglik,

Director, Office of Regulations and Reports Clearance, Office of Legislative and Congressional Affairs, Social Security Administration.

[FR Doc. 2014–26745 Filed 11–12–14; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 1**

[TD 9701]

RIN 1545–BK80

**Arbitrage Rebate Overpayments on
Tax-Exempt Bonds**

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that provide guidance on the recovery of overpayments of arbitrage rebate on tax-exempt bonds and other tax-advantaged bonds. These final regulations provide the deadline for filing a claim for an arbitrage rebate overpayment and certain other rules. These final regulations affect issuers of tax-exempt and tax-advantaged bonds.

DATES: *Effective date:* These regulations are effective on November 13, 2014.

Applicability date: For dates of applicability, see § 1.148–11(l)(4).

FOR FURTHER INFORMATION CONTACT: Timothy Jones at (202) 317–6980 (not a toll-free number).

SUPPLEMENTARY INFORMATION:**Background**

On September 16, 2013, the IRS published a Notice of Proposed Rulemaking (REG–148812–11) in the *Federal Register* (78 FR 56841) (the “Proposed Regulations”). A public hearing was scheduled for February 5, 2014, but later was cancelled because no one requested to speak. However, two comments responding to the Proposed Regulations were received. After

consideration of these comments, the Proposed Regulations are adopted as revised by this Treasury decision.

**Explanation of Provisions and
Summary of Comments**

The final regulations amend the Income Tax Regulations (26 CFR part 1) on the arbitrage investment restrictions on tax-exempt bonds and other tax-advantaged bonds under section 148 of the Internal Revenue Code (Code). Section 1.148–3(i) of the existing Income Tax Regulations provides that an issuer may recover an overpayment of arbitrage rebate and similar payments on an issue of tax-exempt bonds if the issuer establishes to the satisfaction of the Commissioner that the overpayment occurred.

Rev. Proc. 2008–37 (2008–2 CB 137) provides procedures for filing claims for the refund of arbitrage rebate and similar payments and imposes a deadline for filing such claims. In particular, a claim for a refund must be filed no later than two years after the final arbitrage computation date for the issue from which the claim arose. A transition rule applies to issues with a final computation date on or before June 24, 2008. Like the Proposed Regulations, the final regulations include this two-year limitation on filing claims as well as the transition rule.

The final regulations also adopt the rule in the Proposed Regulations that the Commissioner may request additional information to support a claim, specify a date for a return of that information, and deny the claim if the information is not returned by the date specified in the Commissioner’s request or, if the Commissioner grants the issuer an extension to provide the information, by the extension date. Under both the Proposed Regulations and final regulations, if the Commissioner denies a claim because the Commissioner asserts that it was filed after the two-year deadline or that the information requested by the Commissioner was not received by the date specified in the request for such additional information, the issuer may appeal the denial to the Office of Appeals. If the Office of Appeals concludes that the claim was timely filed or the requested information was timely submitted, as applicable, the case will be returned to the Commissioner for further consideration of the merits of the claim.

The final regulations amend the Proposed Regulations to take into account a comment received suggesting that the Proposed Regulations be revised to provide a minimum time period for issuers to respond to any request by the Commissioner for additional

information. In response to this request, the final regulations revise the Proposed Regulations to provide that issuers will be given at least 21 calendar days to respond to a request for additional information. The 21 day period is consistent with the time period provided by the IRS in other instances for submitting additional information. See, for example, section 8.05 of Rev. Proc. 2014–1, 2014–1 IRB 1, 31 (providing taxpayers with 21 days to submit additional information requested by the IRS in connection with the evaluation of a letter ruling request).

Another commenter questioned the Commissioner’s authority to impose the two-year limitation on filing of claims for recovery of an overpayment of arbitrage rebate. The commenter also expressed a concern that an issuer’s right to proceed to court could expire while the issuer’s claim awaits review by the Commissioner.

Treasury and the IRS believe that the Commissioner’s authority to impose the two-year limitation arises from the broad grant of authority to prescribe regulations under section 148(i). In addition, an issuer’s right to proceed to court cannot expire in the manner suggested by the commenter because sections 6532 and 7422 apply to the recovery of arbitrage rebate overpayments. Under section 7422, a claim for the recovery of an alleged arbitrage overpayment cannot be filed in any court until a claim for such amount has been filed with the Secretary. Under section 6532, a proceeding to recover an alleged overpayment of arbitrage generally may not begin before the expiration of six months from the date the claim required by section 7422 has been filed with the Secretary, nor after the expiration of two years from the date the taxpayer is notified of the claim denial. Thus, the final regulations adopt the two-year limitation without change.

Certain changes made by the final regulations to the procedures for processing arbitrage rebate overpayment claims are not reflected in Rev. Proc. 2008–37. As a result, the Treasury Department and the IRS intend to publish guidance updating Rev. Proc. 2008–37 to take into account changes made by the final regulations. Comments are requested on whether other changes should be made to the procedures as part of that guidance.

Effective/Applicability Date

In accordance with section 7805(b)(1)(C) and Rev. Proc. 2008–37, § 1.148–3(i)(3)(i) of the final regulations applies to refund claims arising from an issue of bonds to which § 1.148–3(i) applies and for which the final

computation date is after June 24, 2008. For purposes of applying § 1.148–3(i)(3)(i), issues for which the actual final computation date is on or before June 24, 2008, are deemed to have a final computation date of July 1, 2008. Section 1.148–3(i)(3)(ii) and (iii) of the final regulations apply to refund claims arising from an issue of bonds to which § 1.148–3(i) applies and for which the final computation date is after September 16, 2013.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. It is hereby certified that these regulations will not have a significant economic impact on a substantial number of small entities. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. The final regulations reaffirm or clarify filing deadlines previously published in other administrative guidance. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking that preceded these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business, and no comments were received.

Drafting Information

The principal author of these regulations is Timothy Jones, Office of Associate Chief Counsel (Financial Institutions and Products), IRS. However, other personnel from the IRS and the Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by revising the entry for §§ 1.148–0 through 1.148–11 to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Section 1.148–0 through 1.148–11 also issued under 26 U.S.C. 148(i). * * *

■ **Par. 2.** Section 1.148–0 is amended by adding entries to paragraph (c) Table of contents for §§ 1.148–3(i)(3) and 1.148–11(k) and (l), and revising § 1.148–11 section heading to read as follows:

§ 1.148–0 Scope and table of contents.

* * * * *

(c) * * *

* * * * *

§ 1.148–3 General arbitrage rebate rules.

* * * * *

(i) * * *

(3) Time and manner for requesting refund.

* * * * *

§ 1.148–11 Effective/applicability dates.

* * * * *

(k) [Reserved]

(l) Additional arbitrage guidance updates.

(1) [Reserved]

(2) [Reserved]

(3) [Reserved]

(4) Application.

■ **Par. 3.** Section 1.148–3 is amended by adding paragraph (i)(3) to read as follows:

§ 1.148–3 General arbitrage rebate rules.

* * * * *

(i) * * *

(3) *Time and manner for requesting refund.* (i) An issuer must request a refund of an overpayment (claim) no later than the date that is two years after the final computation date for the issue to which the overpayment relates (the filing deadline). The claim must be made using the form provided by the Commissioner for this purpose.

(ii) The Commissioner may request additional information to support a claim. The issuer must file the additional information by the date specified in the Commissioner's request, which date may be extended by the Commissioner if unusual circumstances warrant. An issuer will be given at least 21 calendar days to respond to a request for additional information.

(iii) A claim described in either paragraph (i)(3)(iii)(A) or (B) of this section that has been denied by the Commissioner may be appealed to the Office of Appeals under this paragraph (i)(3)(iii). Upon a determination in favor of the issuer, the Office of Appeals must return the undeveloped case to the Commissioner for further consideration of the substance of the claim.

(A) A claim is described in this paragraph (i)(3)(iii)(A) if the Commissioner asserts that the claim was filed after the filing deadline.

(B) A claim is described in this paragraph (i)(3)(iii)(B) if the Commissioner asserts that additional information to support the claim was not submitted within the time specified in the request for information or in any extension of such specified time period.

* * * * *

■ **Par. 4.** Section 1.148–11 is amended by revising the section heading and adding reserved paragraph (k) and paragraph (l) to read as follows:

§ 1.148–11 Effective/applicability dates.

* * * * *

(k) [Reserved]

(l) *Additional arbitrage guidance updates.*

(1) [Reserved]

(2) [Reserved]

(3) [Reserved]

(4) *Application.* (i) Section 1.148–3(i)(3)(i) applies to claims arising from an issue of bonds to which § 1.148–3(i) applies and for which the final computation date is after June 24, 2008. For purposes of this paragraph (l)(4), issues for which the actual final computation date is on or before June 24, 2008, are deemed to have a final computation date of July 1, 2008 for purposes of applying § 1.148–3(i)(3)(i). (ii) Section 1.148–3(i)(3)(ii) and (iii) apply to claims arising from an issue of bonds to which § 1.148–3(i) applies and for which the final computation date is after September 16, 2013.

John Dalrymple,
Deputy Commissioner for Services and Enforcement.

Approved: October 17, 2014.

Mark J. Mazur,
Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2014–26738 Filed 11–12–14; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 801

[TD 9703]

RIN 1545–BL89

Balanced System for Measuring Organizational and Employee Performance Within the Internal Revenue Service

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary and final regulations.

SUMMARY: This document contains temporary and final regulations relating

to the IRS system for measuring organizational and employee performance within the IRS, by measuring customer satisfaction, employee satisfaction, and business results. The temporary regulation will eliminate the requirement that information measuring employee satisfaction must be reported to the first-level supervisor in addition to other levels throughout the organization, thus permitting the IRS to stop using the IRS-specific Workforce Questionnaire and, instead, use the same employee satisfaction survey that is used government-wide. The text of the temporary regulation also serves as the text of proposed regulation set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective date:* November 13, 2014.

Applicability date: These regulations are applicable for reporting of employee satisfaction information within the meaning of 26 CFR 801.5T that occurs on or after November 13, 2014.

FOR FURTHER INFORMATION CONTACT: Karen Keller, at (202) 317-5772 (not a toll free number).

SUPPLEMENTARY INFORMATION:

Background

This document amends regulations at 26 CFR Part 801 that implemented sections 1201 and 1204 of the Internal Revenue Service Restructuring and Reform Act of 1998, Public Law 105-206, 112 Stat. 685, 713 (1998) (the Act), and provided rules relating to the establishment of a performance management system.

Explanation of Provision

The temporary regulation contained in this document relates to the Employee Satisfaction Measure, Section 801.5. When the existing regulations were promulgated in 1999, the employee satisfaction measure incorporated the features of an existing employee satisfaction survey, which measured and reported the satisfaction of employees in “pay and duty status” (non-seasonal employees) to first-level supervisors and up through the organization. Other surveys, such as OPM’s Federal Employee Viewpoint Survey (FEVS), which did not exist in 1999 but are now administered government-wide, required reporting of employee satisfaction data to a higher level of agency leadership than first-level supervisors. Although the IRS began conducting the FEVS when it was created by OPM, the IRS modified its

pre-existing survey to enable the continued reporting of data to first-level supervisors as required by the regulation. Currently, the IRS conducts both the FEVS and the survey that complies with Section 801.5. The administration of both surveys has resulted in an undue burden on employees and duplication of effort by the IRS. Accordingly, the temporary regulation eliminates the requirement to use the IRS’ pre-existing survey and permits the reporting of employee satisfaction data from the FEVS to agency leadership, alleviating “survey fatigue” and the unnecessary expenditure of resources and promoting consistency between the IRS and other government agencies when reporting employee satisfaction information.

This regulation is published as a temporary regulation to immediately eliminate the unnecessary requirement for the IRS to administer a second employee satisfaction survey in addition to FEVS. This temporary regulation does not affect taxpayers or taxpayer rights. The temporary regulation only impacts the internal operations of the IRS by eliminating unnecessary burden and expenditure of limited resources.

Special Analyses

It has been determined that as this is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563, a regulatory assessment is not required, and it has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to this regulation. Because this regulation does not impose a collection of information on small entities, the provisions of the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply. Pursuant to section 7805(f) of the Internal Revenue Code, this regulation will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small businesses.

Drafting Information

The principal author of these regulations is Karen F. Keller, Office of Associate Chief Counsel (General Legal Services). However, other personnel from the IRS participated in their development.

List of Subjects in 26 CFR Part 801

Federal employees, Organization and functions (Government agencies).

Amendment to the Regulations

Accordingly, 26 CFR part 801 is amended as follows:

PART 801—BALANCED SYSTEM FOR MEASURING ORGANIZATIONAL AND EMPLOYEE PERFORMANCE WITHIN THE INTERNAL REVENUE SERVICE

■ **Paragraph 1.** The authority citation for Part 801 continues to read in part as follows:

Authority: 5 U.S.C. 9501 * * *

■ **Par. 2.** Section 801.5 is revised to read as follows:

§ 801.5 [Reserved]. For further guidance see § 801.5T.

■ **Par. 3.** Section 801.5T is added to read as follows:

§ 801.5T Employee satisfaction measures (temporary).

(a) The employee satisfaction numerical ratings to be given to a Business Operating Division (BOD) or equivalent office within the IRS will be determined on the basis of information gathered through various methods. For example, questionnaires, surveys, and other information gathering mechanisms may be employed to gather data regarding satisfaction. The information gathered will be used to measure, among other factors bearing upon employee satisfaction, the quality of supervision, and the adequacy of training and support services. All full and part-time permanent employees of a BOD or equivalent office who are in pay and duty status will have an opportunity to provide information regarding employee satisfaction under conditions that guarantee them confidentiality.

(b) *Effective date.* Section 801.5T is effective on or after November 13, 2014 and expires on or before November 10, 2017.

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

Approved: October 14, 2014.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2014-26739 Filed 11-12-14; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 100****[Docket No. USCG–2014–0971]****Special Local Regulation; Southern California Annual Marine Events for the San Diego Captain of the Port Zone****AGENCY:** Coast Guard, DHS.**ACTION:** Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the Hanohano Ocean Challenge special local regulations on January 24, 2015. This marine event occurs on the navigable waters of Mission Bay, in San Diego, California. This action is necessary to provide for safety of the participants, crew, spectators, safety vessels, and general users of the waterway. During the enforcement period, persons and vessels are prohibited from entering into, transiting through, or anchoring within this regulated area unless authorized by the Captain of the Port, or his designated representative.

DATES: The regulations for the marine event listed in 33 CFR 100.1101, Table 1, Item 16, will be enforced from 6:00 a.m. to 2:00 p.m. on January 24, 2015.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Petty Officer Nick Bateman, Waterways Management, U.S. Coast Guard Sector San Diego, CA; telephone (619) 278–7656, email *D11-PF-MarineEventsSanDiego@uscg.mil*.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulations in Mission Bay for the Hanohano Ocean Challenge Nationals in 33 CFR 100.1101, Table 1, Item 16 from 6:00 a.m. to 2:00 p.m.

Under the provisions of 33 CFR 100.1101, persons and vessels are prohibited from entering into, transiting through, or anchoring within the regulated race course area during designated racing times unless authorized by the Captain of the Port, or his designated representative. Persons or vessels desiring to enter into or pass through the regulated area may request permission from the Captain of the Port or designated representative. If permission is granted, all persons and vessels shall comply with the instructions of the Captain of the Port or designated representative. Spectator vessels may safely transit outside the regulated area, but may not anchor, block, loiter, or impede the transit of

participants or official patrol vessels. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in patrol notification and education of the marine event special local regulations.

This notice is issued under authority of 5 U.S.C. 552 (a) and 33 CFR 100.1101. In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via the Local Notice to Mariners, Broadcast Notice to Mariners, and local advertising by the event sponsor. If the Captain of the Port Sector San Diego or his designated representative determines that the regulated area need not be enforced for the full duration stated on this notice, he or she may use a Broadcast Notice to Mariners or other communications coordinated with the event sponsor to grant general permission to enter the regulated area.

Dated: October 28, 2014.

J. S. Spaner,

Captain, U.S. Coast Guard, Captain of the Port San Diego.

[FR Doc. 2014–26916 Filed 11–12–14; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 165****[Docket No. USCG–2014–0950]****RIN 1625–AA00****Safety Zone: Carquinez Strait Cable Repair Operation, Martinez, CA****AGENCY:** Coast Guard, DHS.**ACTION:** Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone in the navigable waters of Carquinez Strait near Martinez, CA in support of a cable repair operation. This temporary safety zone is established to ensure the safety of the mariners and vessels from the dangers associated with the cable repairs being done in Carquinez Strait. Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zone without the permission of the Captain of the Port or a designated representative.

DATES: This rule is effective without actual notice from November 13, 2014 until 8:00 p.m. on December 5, 2014. For the purposes of enforcement, actual notice will be used from 6 a.m. on November 4, 2014, until November 13, 2014.

ADDRESSES: Documents mentioned in this preamble are part of docket USCG–2014–0950. To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type the docket number in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Junior Grade Joshua Dykman, U.S. Coast Guard Sector San Francisco; telephone (415) 399–3585 or email at *D11-PF-MarineEvents@uscg.mil*. If you have questions on viewing or submitting material to the docket, call Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:**Table of Acronyms**

DHS Department of Homeland Security
FR Federal Register
NOAA National Oceanic and Atmospheric Administration
PATCOM U.S. Coast Guard Patrol Commander

A. Regulatory History and Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that it would be impracticable to publish a notice of proposed rulemaking (NPRM) with respect to this rule because immediate action is necessary to protect the public from the dangers associated with the cable repair operation. The cable repairs in the Carquinez Strait are the result of a previous emergency anchorage and are an unforeseeable event that poses an immediate danger to mariners.

For the same reasons, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Providing 30 days notice and delaying its effective date would be impracticable

because immediate action is needed to protect persons, property, and infrastructure from potential damage and safety hazards associated with the cable repair operation in Carquinez Strait in Martinez, CA.

B. Basis and Purpose

The legal basis for the proposed rule is 33 U.S.C 1231; 46 U.S.C Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Public Law 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to establish safety zones.

On October 10, 2014, Coast Guard Sector San Francisco received notification that the Manson 71 Barge would be conducting cable repairs following an anchoring incident in Carquinez Strait. The cable repairs are necessary to ensure that power is not lost to the San Francisco Bay area in the future due to damage done to the cable during the anchoring incident. The safety zone is necessary to protect people, vessels, and other property from the hazards associated with the cable repair operations in Carquinez Strait.

C. Discussion of the Final Rule

The Coast Guard is establishing a temporary safety zone in navigable waters of the Carquinez Strait enclosed within the following points: 38°02'26" N, 122°07'41" W; 38°02'13" N, 122°07'34" W; 38°02'07" N, 122°07'48" W; and 38°02'15" N, 122°08'03" W (NAD83) during the cable repair operations following an anchoring incident in Carquinez Strait. Anchors will be placed at each of the coordinates and the Manson 71 Barge will be tied off in a four-point configuration. This will allow the barge to remain on top of the cable and move up and down to conduct all repairs. This rule is effective and enforceable from 6 a.m. on November 4, 2014 until 8 p.m. on December 5, 2014.

Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zone without the permission of the Captain of the Port or a designated representative. The effect of the safety zones will be to restrict navigation in the vicinity of the Manson 71 Barge while the vessel is conducting a cable repair operation. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the restricted area. These regulations are needed to keep people, vessels, and other property safe by preventing interaction between the Manson 71 Barge and small craft during restricted

maneuvering and to ensure safety of life on the navigable waters.

D. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes and executive orders.

1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders.

We expect the economic impact of this rule will not rise to the level of necessitating a full Regulatory Evaluation. The safety zones are limited in duration, and are limited to a narrowly tailored geographic area. In addition, although this rule restricts access to the waters encompassed by the safety zones, the effect of this rule will not be significant because the local waterway users will be notified via public Broadcast Notice to Mariners to ensure the safety zones will result in minimum impact. The entities most likely to be affected are waterfront facilities, commercial vessels, and pleasure craft engaged in recreational activities.

2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

This rule may affect owners and operators of waterfront facilities, commercial vessels, and pleasure craft engaged in recreational activities and sightseeing. These safety zones would not have a significant economic impact on a substantial number of small entities for the following reasons. These safety zones would be activated, and thus subject to enforcement, for a limited duration. When the safety zones are activated, vessel traffic may coordinate movements around the safety zones by

contacting PATCOM on VHF channel 16. The maritime public will be advised in advance of these safety zones via Broadcast Notice to Mariners.

3. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

4. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and determined that this rule does not have implications for federalism.

6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

7. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

8. Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

9. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

10. Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

11. Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

12. Energy Effects

This action is not a “significant energy action” under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

14. Environment

We have analyzed this rule under Department of Homeland Security

Management Directive 023–01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone of limited size and duration. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, and Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR Part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T11–675 to read as follows:

§ 165.T11–675 Safety zone; Carquinez Strait Cable Repair Operation, Martinez, CA.

(a) *Location.* This temporary safety zone is established for the navigable waters of Carquinez Strait near Martinez, CA as depicted in National Oceanic and Atmospheric Administration (NOAA) Chart 18656. The temporary safety zone in the navigable waters of the Carquinez Strait is enclosed within the following points: 38°02′26″ N, 122°07′41″ W; 38°02′13″ N, 122°07′34″ W; 38°02′07″ N, 122°07′48″ W; and 38°02′15″ N, 122°08′03″ W (NAD83).

(b) *Enforcement period.* The zone described in paragraph (a) of this section will be enforced from 6 a.m. on November 4, 2014 until 8 p.m. on December 5, 2014. The Captain of the Port San Francisco (COTP) will notify the maritime community of periods

during which this zone will be enforced via Broadcast Notice to Mariners in accordance with 33 CFR 165.7.

(c) *Definitions.* As used in this section, “designated representative” means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or local officer designated by or assisting the COTP pursuant to a Memorandum of Understanding with that agency, to assist in the enforcement of the safety zone.

(d) *Regulations.* (1) Entry into, transiting or anchoring within these safety zones is prohibited unless authorized by the COTP or a designated representative.

(2) The safety zones are closed to all vessel traffic, except as may be permitted by the COTP or a designated representative.

(3) Vessel operators desiring to enter or operate within the safety zones must contact the COTP or a designated representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zones must comply with all directions given to them by the COTP or a designated representative. Persons and vessels may request permission to enter the safety zones on VHF–16 or through the 24-hour Command Center at telephone (415) 399–3547.

Dated: October 28, 2014.

Gregory G. Stump,

Captain, U.S. Coast Guard, Captain of the Port San Francisco.

[FR Doc. 2014–26754 Filed 11–12–14; 8:45 am]

BILLING CODE 9110–04–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 14–139; RM–11732; DA 14–1579]

Television Broadcasting Services; Mount Vernon, Illinois

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission issued in response to a petition for rulemaking filed by WPXS, Inc. (“WPXS”), the licensee of WPXS(TV), channel 21, Mount Vernon, Illinois, requesting the substitution of channel 11 for channel 21 at Mount Vernon. WPXS filed comments reaffirming its interest in the proposed channel substitution and states that it will apply for the channel if allotted,

and promptly construct if authorized. Substituting channel 11 for channel 21 will further the Commission's goal of clearing UHF spectrum for new uses and allow WPXS to provide improved service to viewers, which serves the public interest.

DATES: This rule is effective December 15, 2014.

FOR FURTHER INFORMATION CONTACT:

Joyce Bernstein, *Joyce.Bernstein@fcc.gov*, Media Bureau, (202) 418-1647.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MB Docket No. 143-139, adopted October 30, 2014, and released October 31, 2014. The full text of this document is available for public inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY-A257, 445 12th Street SW., Washington, DC, 20554. This document will also be available via ECFS (<http://fjallfoss.fcc.gov/ecfs/>). This document may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street SW., Room CY-B402, Washington, DC 20554, telephone 1-800-478-3160 or via the company's Web site, <http://www.bcpweb.com>. To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to fcc504@fcc.gov or call the Consumer & Governmental Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (tty).

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104-13. In addition, therefore, it does not contain any information collection burden "for small business concerns with fewer than 25 employees," pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107-198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

The Commission will send a copy of this Report and Order in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Barbara A. Kreisman,
Chief, Video Division, Media Bureau.

Final Rule

For the reasons discussed in the preamble, the Federal Communications

Commission amends 47 CFR Part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

- 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336, and 339.

§ 73.622 [Amended]

- 2. Section 73.622(i), the Post-Transition Table of DTV Allotments under Illinois is amended by removing channel 21 and adding channel 11 at Mount Vernon.

[FR Doc. 2014-26796 Filed 11-12-14; 8:45 am]

BILLING CODE 6712-01-P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 217 and 219

Defense Federal Acquisition Regulation Supplement; Technical Amendments

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is making technical amendments to the Defense Federal Acquisition Regulation Supplement (DFARS) to provide needed editorial changes.

DATES: Effective November 13, 2014.

FOR FURTHER INFORMATION CONTACT: Mr. Manuel Quinones, Defense Acquisition Regulations System, OUSD(AT&L)DPAP(DARS), Room 3B941, 3060 Defense Pentagon, Washington, DC 20301-3060. Telephone 571-372-6088; facsimile 571-372-6094.

SUPPLEMENTARY INFORMATION:

This final rule amends the DFARS as follows:

1. Directs contracting officers to additional procedures and guidance by adding references at 217.207 to DFARS PGI 217.207.
2. Corrects paragraph designation at 219.201.

List of Subjects in 48 CFR Parts 217 and 219

Government procurement.

Manuel Quinones,
Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 217 and 219 are amended as follows:

- 1. The authority citation for 48 CFR parts 217 and 219 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 217—SPECIAL CONTRACTING METHODS

- 2. Revise section 217.207 to read as follows:

217.207 Exercise of options.

(c) In addition to the requirements at FAR 17.207(c), exercise an option only after determining that the contractor's record in the System for Award Management database is active and the contractor's Data Universal Numbering System (DUNS) number, Commercial and Government Entity (CAGE) code, name, and physical address are accurately reflected in the contract document. See PGI 217.207 for the requirement to perform cost or price analysis of spare parts prior to exercising any option for firm-fixed-price contracts containing spare parts.

PART 219—SMALL BUSINESS PROGRAMS

219.201 [Amended]

- 3. Amend section 219.201 by redesignating paragraphs (d) and (e) as paragraphs (c) and (d) respectively.

[FR Doc. 2014-26599 Filed 11-12-14; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS-HQ-ES-2014-0055; 4500030113]

RIN 1018-BA63

Endangered and Threatened Wildlife and Plants; Adding 20 Coral Species to the List of Endangered and Threatened Wildlife

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), in accordance with the Endangered Species Act of 1973, as amended (Act), are amending the List of Endangered and Threatened Wildlife (List) by adding 20 species of corals: Boulder star coral (*Orbicella franksi*), lobed star coral (*Orbicella annularis*), mountainous star coral (*Orbicella faveolata*), pillar coral (*Dendrogyra cylindrus*), rough cactus

coral (*Mycetophyllia ferox*), *Acropora globiceps*, *Acropora jacquelineae*, *Acropora lokani*, *Acropora pharaonis*, *Acropora retusa*, *Acropora rudis*, *Acropora speciosa*, *Acropora tenella*, *Anacropora spinosa*, *Euphyllia paradivisia*, *Isopora crateriformis*, *Montipora australiensis*, *Pavona diffluens*, *Porites napopora*, and *Seriatopora aculeata*. These amendments are based on previously published determinations by the National Marine Fisheries Service (NMFS) of the National Oceanic and Atmospheric Administration, Department of Commerce, which has jurisdiction for these species.

DATES: This rule is effective November 13, 2014. *Applicability date:* The 20 coral listings were applicable as of October 10, 2014.

FOR FURTHER INFORMATION CONTACT: Douglas Krofta, Chief, Branch of Endangered Species Listing, U.S. Fish and Wildlife Service, MS-ES, 5275 Leesburg Pike, Falls Church, VA 22041-3803; 703-358-2171.

SUPPLEMENTARY INFORMATION:

Background

In accordance with the Act (16 U.S.C. 1531 et seq.) and Reorganization Plan No. 4 of 1970 (35 FR 15627; October 6, 1970), NMFS has jurisdiction over the marine and anadromous taxa identified in this rule. Under section 4(a)(2) of the Act, NMFS must decide whether a species under its jurisdiction should be classified as an endangered or threatened species. NMFS makes these determinations via its rulemaking process. We, the Service, are then responsible for publishing final rules to amend the List in title 50 of the Code of Federal Regulations (CFR) at 50 CFR 17.11(h).

On December 7, 2012, NMFS published a proposed rule (77 FR 73220) to list 66 petitioned coral species, 12 as endangered and 54 as threatened, and to reclassify from threatened to endangered two coral species (elkhorn coral (*Acropora*

palmata) and staghorn coral (*Acropora cervicornis*)) already listed under the Act. NMFS solicited public comments on the proposed rule through March 7, 2013. On September 20, 2013, NMFS published a notice of 6-month extension of the deadline for the final coral species' determinations because of substantial disagreement regarding the sufficiency and accuracy of the data and analyses relevant to the proposed listing determinations (78 FR 57835).

On September 10, 2014, NMFS published a final rule (79 FR 53852) to list 20 of the 66 proposed coral species as threatened species. The listing of the 20 species was effective October 10, 2014. In that same rule, NMFS also determined that elkhorn coral and staghorn coral did not warrant reclassification from threatened to endangered. However, we revise the elkhorn coral and staghorn coral listings in this rule to make the information in the Historic Range column consistent with the other coral entries; the listing status of threatened remains unchanged for these two species.

In the September 10, 2014, final rule (79 FR 53852), NMFS addressed all public comments received in response to the proposed rule. By publishing this final rule, we are simply taking the necessary administrative step to codify these changes in the List in 50 CFR 17.11(h).

Administrative Procedure Act

Because NMFS provided a public comment period on the proposed rules for these taxa, and because this action of the Service to amend the List in accordance with the determination by NMFS is nondiscretionary, the Service finds good cause that the notice and public comment procedures of 5 U.S.C. 553(b) are unnecessary for this action. We also find good cause under 5 U.S.C. 553(d)(3) to make this rule effective immediately. The NMFS rules extended protection under the Act to these species and listed them in 50 CFR parts 223 and 224; this rule is an administrative action to add the species

to the List of Endangered and Threatened Wildlife at 50 CFR 17.11(h). The public would not be served by delaying the effective date of this rulemaking action.

Required Determinations

National Environmental Policy Act

We have determined that an environmental assessment, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Act. We outlined our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

- 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; 4201–4245, unless otherwise noted.

- 2. Amend § 17.11(h) under Corals by:
- a. Revising the entries for “Coral, elkhorn” and “Coral, staghorn” to read as set forth below; and
 - b. Adding 20 entries in alphabetical order for: “Coral, [no common name]” (15 entries); “Coral, boulder star”; “Coral, lobed star”; “Coral, mountainous star”; “Coral, pillar”; and “Coral, rough cactus”, to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
*	*	*	*	*	*		*
Corals							
Coral, [no common name].	<i>Acropora globiceps</i> .	U.S.A. (Guam, Commonwealth of the Northern Mariana Islands, Pacific Remote Island Areas, American Samoa); and wider Indo-Pacific.	Entire	T	853	NA	NA
Coral, [no common name].	<i>Acropora jacquelineae</i> .	U.S.A. (American Samoa); and wider Indo-Pacific.	Entire	T	853	NA	NA

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
Coral, [no common name].	<i>Acropora lokani</i>	Indo-Pacific	Entire	T	853	NA	NA
Coral, [no common name].	<i>Acropora pharaonis</i> .	Indo-Pacific	Entire	T	853	NA	NA
Coral, [no common name].	<i>Acropora retusa</i> .	U.S.A. (Guam, Commonwealth of the Northern Mariana Islands, Pacific Remote Island Areas, American Samoa); and wider Indo-Pacific.	Entire	T	853	NA	NA
Coral, [no common name].	<i>Acropora rudis</i>	U.S.A. (American Samoa); and wider Indo-Pacific.	Entire	T	853	NA	NA
Coral, [no common name].	<i>Acropora speciosa</i> .	U.S.A. (Pacific Remote Island Areas, American Samoa); and wider Indo-Pacific.	Entire	T	853	NA	NA
Coral, [no common name].	<i>Acropora tenella</i> .	Indo-Pacific	Entire	T	853	NA	NA
Coral, [no common name].	<i>Anacropora spinosa</i> .	Indo-Pacific	Entire	T	853	NA	NA
Coral, [no common name].	<i>Euphyllia paradivisa</i> .	U.S.A. (American Samoa); and wider Indo-Pacific.	Entire	T	853	NA	NA
Coral, [no common name].	<i>Isopora crateriformis</i> .	U.S.A. (American Samoa); and wider Indo-Pacific.	Entire	T	853	NA	NA
Coral, [no common name].	<i>Montipora australiensis</i> .	Indo-Pacific	Entire	T	853	NA	NA
Coral, [no common name].	<i>Pavona diffluens</i> .	Indo-Pacific	Entire	T	853	NA	NA
Coral, [no common name].	<i>Porites napopora</i> .	Indo-Pacific	Entire	T	853	NA	NA
Coral, [no common name].	<i>Seriatopora aculeata</i> .	U.S.A. (Guam, Commonwealth of the Northern Mariana Islands); and wider Indo-Pacific.	Entire	T	853	NA	NA
Coral, boulder star.	<i>Orbicella franksi</i> .	U.S.A. (FL, PR, USVI, Gulf of Mexico); and wider Caribbean.	Entire	T	853	NA	NA
Coral, elk-horn.	<i>Acropora palmata</i> .	U.S.A. (FL, PR, USVI); and wider Caribbean.	Entire	T	853	226.216	223.208
Coral, lobed star.	<i>Orbicella annularis</i> .	U.S.A. (FL, PR, USVI, Gulf of Mexico); and wider Caribbean.	Entire	T	853	NA	NA
Coral, mountainous star.	<i>Orbicella faveolata</i> .	U.S.A. (FL, PR, USVI, Gulf of Mexico); and wider Caribbean.	Entire	T	853	NA	NA
Coral, pillar	<i>Dendrogyra cylindrus</i> .	U.S.A. (FL, PR, USVI); and wider Caribbean.	Entire	T	853	NA	NA
Coral, rough cactus.	<i>Mycetophyllia ferox</i> .	U.S.A. (FL, PR, USVI); and wider Caribbean.	Entire	T	853	NA	NA
Coral, staghorn.	<i>Acropora cervicornis</i> .	U.S.A. (FL, PR, USVI); and wider Caribbean.	Entire	T	853	226.216	223.208

* * * * *

Dated: November 4, 2014.

Stephen Guertin,*Acting Director, U.S. Fish and Wildlife Service.*

[FR Doc. 2014-26893 Filed 11-12-14; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 300**

[Docket No. 140131088-4913-02]

RIN 0648-BD94

International Fisheries; Western and Central Pacific Fisheries for Highly Migratory Species; Fishing Effort Limits in Purse Seine Fisheries for 2014**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.**ACTION:** Final rule.

SUMMARY: NMFS issues regulations under authority of the Western and Central Pacific Fisheries Convention Implementation Act (WCPFC Implementation Act) to revise the 2014 limit on fishing effort by U.S. purse seine vessels in the U.S. exclusive economic zone (U.S. EEZ) and on the high seas between the latitudes of 20° N. and 20° S. in the area of application of the Convention on the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (Convention). The total limit for 2014 is revised from 2,588 fishing days to 1,828 fishing days. This action is necessary for the United States to implement provisions of a conservation and management measure (CMM) adopted by the Commission for the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (Commission) and to satisfy the obligations of the United States under the Convention, to which it is a Contracting Party.

DATES: This rule is effective December 15, 2014.**ADDRESSES:** Copies of supporting documents prepared for this final rule, including the regulatory impact review (RIR) and the Supplemental Information Report prepared for National Environmental Policy Act (NEPA) purposes, as well as the proposed rule, are available via the Federal e-Rulemaking Portal, at www.regulations.gov (search for Docket

ID NOAA-NMFS-2014-0081). Those documents, and the small entity compliance guide prepared for this final rule, are also available from NMFS at the following address: Michael D. Tosatto, Regional Administrator, NMFS, Pacific Islands Regional Office (PIRO), 1845 Wasp Blvd., Building 176, Honolulu, HI 96818. The initial regulatory flexibility analysis (IRFA) and final regulatory flexibility analysis (FRFA) prepared under the authority of the Regulatory Flexibility Act (RFA) are included in the proposed rule and this final rule, respectively.

FOR FURTHER INFORMATION CONTACT: Tom Graham, NMFS PIRO, 808-725-5032.**SUPPLEMENTARY INFORMATION:****Background**

On July 25, 2014, NMFS published a proposed rule in the *Federal Register* (79 FR 43373) to revise regulations at 50 CFR part 300, subpart O, to implement a decision of the Commission. The proposed rule was open for public comment through August 25, 2014.

This final rule is issued under the authority of the WCPFC Implementation Act (16 U.S.C. 6901 *et seq.*), which authorizes the Secretary of Commerce, in consultation with the Secretary of State and the Secretary of the Department in which the United States Coast Guard is operating (currently the Department of Homeland Security), to promulgate such regulations as may be necessary to carry out the obligations of the United States under the Convention, including the decisions of the Commission. The authority to promulgate regulations has been delegated to NMFS.

This final rule implements for U.S. fishing vessels some of the purse seine-related provisions of the Commission's Conservation and Management Measure (CMM) 2013-01, "Conservation and Management Measure for Bigeye, Yellowfin and Skipjack Tuna in the Western and Central Pacific Ocean." The preamble to the proposed rule includes detailed background information, including on the Convention and the Commission, the provisions of CMM 2013-01 being implemented in this rule, and the bases for the proposed regulations, which is not repeated here.

New Requirements

This final rule revises the existing limit on the number of fishing days that may be used by U.S. purse seine vessels in 2014 in an area called the Effort Limit Area for Purse Seine (ELAPS). The ELAPS includes all areas of the high seas and U.S. EEZ within the Convention Area between the latitudes of 20° North and 20° South (but not the

U.S. territorial sea). The limit is revised from 2,588 fishing days to 1,828 fishing days.

Once NMFS determines during 2014 that, based on available information, the limit is expected to be reached by a specific future date, NMFS will issue a notice in the *Federal Register* announcing the closure of the U.S. purse seine fishery in the ELAPS starting on that specific future date. Upon any closure, it will be prohibited to use a U.S. purse seine vessel to fish in the ELAPS through the end of the calendar year. NMFS will publish the notice at least seven calendar days before the effective date of the closure to provide fishermen advance notice of the closure.

Comments and Responses

NMFS received three sets of comments on the proposed rule and supporting documents. The comments are summarized below, followed by responses from NMFS.

Comment 1: I support this rule to reduce fishing days in order to conserve our fish stocks.

Response: NMFS acknowledges the comment.

Comment 2: I fail to see how the proposed rule would protect the stock with the Asian and Pacific Island countries continuing to add boats to their Pacific Ocean fleets while the United States plays into their hands and continues to strangle-hold our fleet. Soon, all fish sold in the U.S. market will be sourced from foreign vessels, which are less-than-ideal role models.

These areas are highly regulated, as U.S. boats must be U.S.-built and have a fisheries endorsement to fish in these areas; and that is less than one third of the U.S. fleet. My boat is U.S.-built but cannot fish in U.S. waters. But instead of our government helping me to gain access, it just adds more unnecessary regulations.

There are countries that continue to add boats and to fish on fish aggregating devices even during the closure while not living up to their responsibilities that are already in place.

I propose to postpone implementing the limit until a long-term solution is agreed and implemented by all in the Commission, as this is not a permanent solution. These areas are not in danger from U.S. boats. However, the U.S. boats are the eyes and ears, and have in the past found and reported illegal, unreported, and unregulated fishing in the U.S. EEZ. The U.S. boats do not receive any reimbursement for time or

fuel for this reporting, but it is the right thing to do.

While areas continue to be closed off, we are only hurting the stocks as we are allowing the Pacific Island Parties to focus international fishing efforts into their exclusive economic zones for purely economic reasons, rather than focusing on efforts to truly conserve, by limiting vessels. Remember these are highly migratory species. I compare the focusing of effort to sunlight: Normally, it will not hurt you, but if you focus sunlight through a magnifying glass, it will burn; this is what is being done by driving effort into smaller areas.

Postpone this proposed rule, or better, cancel it, as these areas are already regulated by the United States. The problem can be addressed and solved on the international level rather than strangle-holding our fleet while others continue to add boats, skirt regulations, and worst of all, not even enforce what is already in place.

Support the U.S. fleet and the stock and push for vessel limits on all fleets, as the catch phrase “domestic fleet” is simply Asian boats that are flagged in the islands. Work with the U.S. fleet instead of against it; we are the highest regulated fleet in the world, and we are ahead of the curve, as we have already dropped our fishing efforts (numbers of boats) in the 1980s when the U.S. Tuna Treaty (Treaty on Fisheries between the Governments of Certain Pacific Island States and the Government of the United States of America, also known as the South Pacific Tuna Treaty, or SPTT) was signed, well ahead of other fleets that are continuing to add effort.

Let's be logical and work together and protect the stock and our food source.

Response: NMFS recognizes that if the United States imposes Commission-mandated requirements on its vessels, such as limits on fishing effort, and other members of the Commission do not do the same—despite being required to do so under the Convention—for their vessels, U.S. fishing vessels can be put at a competitive disadvantage relative to the fishing vessels of other members. If that disadvantage is severe enough, U.S. vessels could supply less product than they formerly did, resulting in shifts in the sources of fish sold in U.S. and other markets. NMFS also recognizes that if other Commission members fail to fully implement the decisions of the Commission, such as the provisions of CMM 2013–01, those decisions are less likely to achieve their fish stock conservation objectives. However, in order to satisfy the obligations of the United States as a party to the Convention and member of the Commission, NMFS is required to

implement the Commission-mandated fishing effort limits for U.S. purse seine vessels. Accordingly, the commenter's proposal to postpone or cancel implementation would not satisfy U.S. obligations under the Convention. NMFS is proceeding with implementation through this final rule. NMFS also notes that the United States, as a member of the Commission, is contributing to and has prioritized the development of the Commission's compliance monitoring scheme, with the aim of improving compliance with Commission decisions by all its members.

Comment 3: The American Tunaboat Association (ATA) is composed of the owners of all U.S.-flag purse seine vessels fishing in the western Pacific Ocean. There will be a direct and significant impact on the U.S. fleet should this proposed rule be finalized as written.

The proposed reduction in allowable fishing days in the ELAPS from 2,588 to 1,828 would be a substantial loss of fishing opportunities for U.S. vessels at a time of great uncertainty regarding fishing access under the SPTT. The ATA understands that there may be little flexibility in implementing the Commission measure establishing a fishing day limit on the high seas, but we note that there is flexibility for the U.S. EEZs. Therefore, in combining the two areas as the ELAPS, a level higher than 1,828 fishing days is justified.

The ELAPS limits are not based on science relative to the conservation of the tuna stocks. The science provider to the Commission has not recommended, as a conservation measure, limits on catches of tunas on the high seas, or in any particular economic zones. This is an important point, because that truth provides the United States with more flexibility in the manner in which it regulates the U.S. fleet. For example, the United States could establish a larger number for allowable catches in the U.S. EEZ based on using certain past high years as base years. Given the variability in the availability of highly migratory stocks in different areas during different years, and the relevance of the fishing strategies that are employed in any given year, such an approach would not be unreasonable.

The ATA urges NMFS to develop such an alternative approach and provide for a larger ELAPS limit than 1,828 fishing days. We also believe that, if all fishing by purse seine vessels is prohibited in these remote island areas as a result of an expansion of the Pacific marine monuments, as is being contemplated by the Administration (an action strongly opposed by ATA), the

consequent lost fishing opportunities should be compensated for by allowing more fishing on the same stocks elsewhere; that is, on the high seas. From a science or conservation point of view, there would be no detriment to the tuna stocks from such an approach.

Response: NMFS acknowledges that the proposed rule could have direct economic impacts on participants in the U.S. purse seine fleet in the western and central Pacific Ocean (WCPO). As described in the RIR and IRFA prepared for this action, the impacts could be minor or substantial, depending on such factors as the length of the closure of the ELAPS in the event the limit is reached, whether the EEZs of the FFA members remain available for fishing during such a closure, and oceanic conditions.

This rule implements certain provisions of CMM 2013–01, which directs coastal members like the United States to “establish effort limits, or equivalent catch limits for purse seine fisheries within their EEZs that reflect the geographical distributions of skipjack, yellowfin, and bigeye tunas, and are consistent with the objectives for those species” (excerpt from paragraph 23 of CMM 2013–01). CMM 2013–01 further requires, “Those coastal States that have already notified limits to the Commission shall restrict purse seine effort and/or catch within their EEZs in accordance with those limits” (excerpt from paragraph 23 of CMM 2013–01). Because the United States has previously notified the Commission of its purse seine effort limits for the U.S. EEZ since the limits were first established in 2009 (in a final rule published August 4, 2009; 74 FR 38544), the United States is obligated to continue to apply the same limits for the U.S. EEZ. Thus, CMM 2013–01 does not change the applicable purse seine fishing effort limit for the U.S. EEZ, and for that reason NMFS does not agree that there is flexibility in the limit for the U.S. EEZ or that a limit for the ELAPS of more than 1,828 fishing days is justified in this rule to implement provisions of CMM 2013–01.

Finally, on September 25, 2014, President Obama issued Proclamation 9173 extending the boundaries of the Pacific Remote Islands Marine National Monument around Jarvis Island, Wake Island, and Johnston Atoll to the outer limit of the U.S. EEZ. Under the Proclamation, commercial fishing is prohibited in the expansion area. NMFS acknowledges that the prohibition of commercial fishing within the expansion area will limit the fishing grounds available to U.S. purse seine vessels; however, we note that the expansion area represents a small

fraction of the U.S. purse seine fleet's typical fishing grounds in the WCPO.

Changes From the Proposed Rule

No changes from the proposed rule have been made in this final rule.

Classification

The Administrator, Pacific Islands Region, NMFS, has determined that this final rule is consistent with the WCPFC Implementation Act and other applicable laws.

Executive Order 12866

This final rule has been determined to be not significant for purposes of Executive Order 12866.

Regulatory Flexibility Act (RFA)

A FRFA was prepared. The FRFA incorporates the IRFA prepared for the proposed rule. The analysis in the IRFA is not repeated here in its entirety.

A description of the action, why it is being considered, and the legal basis for this action are contained in the preamble of the proposed rule and in the **SUMMARY** and **SUPPLEMENTARY INFORMATION** sections of this final rule, above. The analysis follows.

Significant Issues Raised by Public Comments in Response to the IRFA

NMFS did not receive any comments on the IRFA itself, but two sets of comments could pertain to small entities. See Comments 2 and 3 on the proposed rule, and NMFS' responses, above.

Description of Small Entities to Which the Rule Will Apply

Small entities include "small businesses," "small organizations," and "small governmental jurisdictions." The Small Business Administration (SBA) has established size standards for all major industry sectors in the United States, including commercial finfish harvesters (NAICS code 114111). A business primarily involved in finfish harvesting is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of \$20.5 million for all its affiliated operations worldwide.

This final rule will apply to owners and operators of U.S. purse seine vessels used for fishing in the Convention Area. The number of affected vessels is the number licensed under the Treaty on Fisheries between the Governments of Certain Pacific Island States and the Government of the United States of America (South Pacific Tuna Treaty, or

SPTT). The current number of licensed vessels is 40, the maximum number of licenses available under the SPTT (excluding joint-venture licenses, of which there are five available under the SPTT, none of which have ever been applied for or issued).

Based on (limited) available financial information about the affected fishing vessels and the SBA's small entity size standards for commercial finfish harvesters, and using individual vessels as proxies for individual businesses, NMFS believes that all the affected fish harvesting businesses are small entities. As stated above, there are currently 40 purse seine vessels in the affected purse seine fishery. Neither gross receipts nor ex-vessel price information specific to the 40 vessels are available to NMFS. Average annual receipts for each of the 40 vessels during the last 3 years for which reasonably complete data are available (2010–2012) were estimated as follows: The vessel's reported retained catches of skipjack tuna, yellowfin tuna, and bigeye tuna in each year were each multiplied by an indicative Asia-Pacific regional cannery price for that species and year (developed by the Pacific Islands Forum Fisheries Agency and available at <https://www.ffa.int/node/425#attachments>); the products were summed across species for each year; and the sums were averaged across the 3 years. The estimated average annual receipts for each of the 40 vessels were less than the \$20.5 million threshold used to classify businesses as small entities under the SBA size standard for finfish harvesting businesses.

Recordkeeping, Reporting, and Other Compliance Requirements

The final rule will not establish any new reporting or recordkeeping requirements within the meaning of the Paperwork Reduction Act. The classes of small entities subject to the requirements and the types of professional skills necessary to fulfill each of the requirements are described in the IRFA.

Disproportionate Impacts

There would be no disproportionate economic impacts between small and large entities operating purse seine vessels as a result of this final rule. Furthermore, there would be no disproportionate economic impacts based on vessel size, gear, or homeport.

Steps Taken To Minimize the Significant Economic Impacts on Small Entities

In previous rulemakings to establish or revise U.S. purse seine fishing effort limits in the ELAPS in accordance with

Commission decisions, NMFS considered a number of alternatives. The alternatives included different time scales for the limits (e.g., single-year versus multiple-year limits); whether separate limits or a combined limit would be established in the U.S. EEZ and high seas portions of the ELAPS; whether the limit(s) would be allocated to individual vessels; and different magnitudes of the limit(s).

The first category of alternatives, time scales, is not relevant here because the objective is to implement the required fishing effort limit for 2014 only.

The second category of alternatives—whether or not to break up the ELAPS limit into separate limits for the U.S. EEZ and the high seas portions of the ELAPS—would provide less operational flexibility for affected purse seine vessels, and thus be more constraining and costly than the proposed limit. It is rejected for that reason.

The third category of alternatives, allocating the limit among individual vessels, would likely alleviate any adverse impacts of a race-to-fish that might occur as a result of establishing the competitive fishing effort limits as in the proposed rule. As described in the IRFA, those potential impacts include lower prices for landed product, as well as risks to performance and safety stemming from fishing during sub-optimal times. Those impacts, however, are expected to be minor. Furthermore, developing the necessary allocation criteria and procedures would be a substantial and lengthy process that probably could not be completed in time to implement this limit for 2014. For these reasons, this alternative is rejected.

Regarding the fourth category of alternatives (the magnitude of the limits), NMFS considered, for the 2013 rule that established the 2013 ELAPS limit and existing 2014 ELAPS limit, both smaller and larger limits for the ELAPS. Smaller limits, being more constraining and costly to affected fishing businesses, are not considered further here. With respect to larger limits, in the 2013 rule, NMFS considered an alternative that would be based in part on the fleet's greatest annual level of fishing effort in the U.S. EEZ (on an average per-vessel basis, then expanded to a 40-vessel-equivalent) during the 1997–2010 time period. For this rule, NMFS considered an alternative using the same approach considered in the 2013 rule. Using that approach, the limit in the U.S. EEZ would be 1,655 fishing days, and when combined with the high seas limit of 1,270 fishing days, the total ELAPS limit would be 2,925 fishing days. Because

this alternative limit is greater and thus less constraining than a limit of 1,828 fishing days (as well as the existing limit of 2,588 fishing days), the costs of complying with this alternative would be less than or equal to those of the proposed limit of 1,828 fishing days. This alternative is rejected because it would depart from the way that the effort limits established for the period 2009–2013 were determined. The approach used in formulating the limit in this final rule is the same as that used to establish ELAPS limits in the 2009 rule, the 2011 rule, and the 2013 rule, and affected entities have been exposed to the impacts of those limits for the past 5 years. Furthermore, as explained in NMFS' response to Comment 3, above, CMM 2013–01 does not all allow for higher purse seine effort limits in the U.S. EEZ than those already notified to the Commission.

The alternative of taking no action at all, which would leave the existing 2014 ELAPS limit of 2,588 fishing days in place, is rejected because it would fail to accomplish the objective of the WCPFC Implementation Act or satisfy the obligations of the United States as a Contracting Party to the Convention.

Small Entity Compliance Guide

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as "small entity compliance guides." The agency shall explain the actions a small entity is required to take to comply with a rule or group of rules. As part of this rulemaking process, a small entity compliance guide has been prepared. The guide will be sent to permit and license holders in the affected fisheries. The guide and this final rule will also be available at www.fpir.noaa.gov and by request from NMFS PIRO (see ADDRESSES).

List of Subjects in 50 CFR Part 300

Administrative practice and procedure, Fish, Fisheries, Fishing, Marine resources, Reporting and recordkeeping requirements, Treaties.

Dated: November 6, 2014.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 300 is amended as follows:

PART 300—INTERNATIONAL FISHERIES REGULATIONS

■ 1. The authority citation for 50 CFR part 300, subpart O, continues to read as follows:

Authority: 16 U.S.C. 6901 *et seq.*

■ 2. In § 300.223, paragraph (a)(1) is revised to read as follows:

§ 300.223 Purse seine fishing restrictions.

* * * * *

(a) * * *

(1) For calendar year 2014 there is a limit of 1,828 fishing days.

* * * * *

[FR Doc. 2014–26830 Filed 11–12–14; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 141002822–4933–01]

RIN 0648–BE56

Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Northeast Groundfish Fishery; Fishing Year 2014; Emergency Gulf of Maine Cod Management Measures

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; interim action; request for comments.

SUMMARY: This temporary rule implements commercial and recreational fishery management measure changes for Gulf of Maine cod protection in response to a recent updated assessment of the status of this severely depleted stock. The measures of this interim rule are necessary to reduce fishing mortality on GOM cod and to provide additional stock and spawning protection. The intended effect of these interim measures are to decrease fishing year 2014 catch so that overfishing is reduced and protect the stock until more permanent measures can be developed by the New England Fishery Management Council (Council).

DATES: Effective November 13, 2014, until May 12, 2015. Comments must be received by December 13, 2014.

ADDRESSES: You may submit comments, identified by NOAA–NMFS–2014–0125, by any of the following methods:

- **Electronic submissions:** Submit all electronic public comments via the Federal eRulemaking Portal. Go to www.regulations.gov /#!docketDetail;D=NOAA-NMFS-2014-0125, click the "Comment Now!" icon, complete the required fields, and enter or attach your comments.

- **Mail:** Submit written comments to John K. Bullard, Regional Administrator, National Marine Fisheries Service, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope, "Comments on the GOM Cod Interim Action."

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on www.regulations.gov without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

Copies of an environmental assessment (EA) prepared by the Greater Atlantic Regional Fisheries Office (GARFO) and Northeast Fisheries Science Center (Center) for this rulemaking are available from John K. Bullard, Regional Administrator, National Marine Fisheries Service, 55 Great Republic Drive, Gloucester, MA 01930. The EA is also available via the Internet at www.nero.noaa.gov/sfd/sfdmulti.html.

FOR FURTHER INFORMATION CONTACT: Michael Ruccio, Fishery Policy Analyst, phone: 978–281–9104.

SUPPLEMENTARY INFORMATION:

Interim Measures

At the request of the Council, and in response to a recent updated assessment of Gulf of Maine (GOM) cod indicating that this stock is at a historically low abundance level, NMFS, on behalf of the Secretary of Commerce, is taking interim action to implement GOM cod fishing mortality reductions and other management measures designed to reduce overfishing, protect aggregations and spawning, and keep GOM cod on a rebuilding trajectory. These actions are being implemented as interim measures under the authority provided in section 305(c) of the Magnuson-Stevens Fishery

Conservation and Management Act (Magnuson-Stevens Act) with the expectation that the Council will recommend additional permanent measures for fishing year 2015 and beyond to end overfishing and rebuild this stock. The measures are summarized here with additional detail provided under specific headings that appear below in this rule's preamble. The measures are:

1. Time and area closures applicable to federally permitted vessels using commercial and recreational fishing gear capable of catching GOM cod;

2. A 200-lb (90.7-kg) GOM cod trip limit both the common pool and sector vessels;

3. Changes to commercial fishing declarations prohibiting sector vessels declaring into the GOM Broad Stock Area from fishing in another broad stock area on the same trip;

4. Prohibition on the possession of recreationally caught GOM cod (applies to entire GOM Broad Stock Area); and

5. Revocation of a previously authorized GOM exemption that allowed sector vessels declared into the gillnet fishery to use more gillnets.

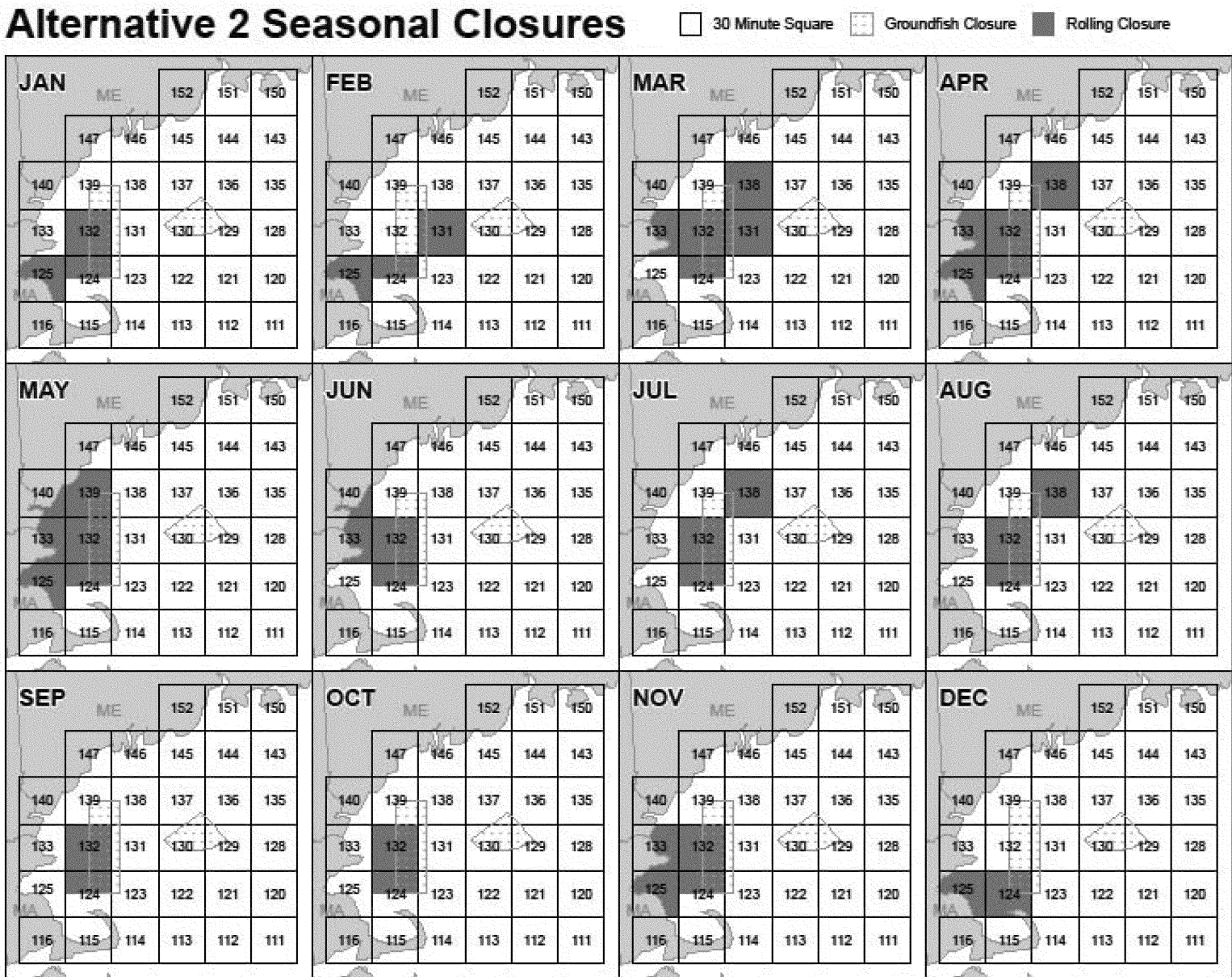
This rule implements these measures for an initial 180 days, as authorized by section 305(c) of the Magnuson-Stevens Act. These measures may be extended, or modified, as needed, for an additional 186 days pursuant to section 305(c) of the Magnuson-Stevens Act. Any modification or extension will be published in the **Federal Register**. This rule is consistent with the requirements established under section 305(c) and NMFS policy guidance for emergency rulemaking.

Seasonal Interim Closure Areas

The following areas are closed to federally permitted vessels using fishing gear (commercial and recreational,

including party and charter) capable of catching GOM cod, which does not include "exempted gear" as defined in § 648.2, in the times and areas indicated in Figure 1, beginning on the date this rule is published in the **Federal Register**. These measures temporarily replace and expand on the existing GOM rolling closures. Although the closures will be in effect upon this rule's publication, we will delay implementing the closure areas for 2 weeks following publication of this rule to allow fixed gear (gillnets, longline) time to remove fishing gear from the November closure areas (i.e., 30-minute squares 132, 133, 125, and the northern half of 124). The portions of the year-round Western Gulf of Maine (WGOM) Closure Area not otherwise closed by the 30-minute squares that overlap the area in this action will continue remain accessible for federally permitted party and charter vessels through a Letter of Authorization.

Figure 1. Seasonal Interim Closed Areas, Closed to all Fishing Gear Capable of Catching GOM Cod, by Month.



Seasonal Interim Closure Area Rationale

Three objectives were used in evaluating areas for interim closures: Reducing fishing mortality by reducing

GOM cod commercial and recreational catch; protecting core areas where the remaining GOM cod stock is believed to be located; and protecting areas of likely cod spawning activities. These objectives were analyzed in the context

of not closing down the entire GOM so as to allow some harvesting of other groundfish stocks but still reducing mortality and fishing on cod while the Council develops more permanent measures for Framework Adjustment 53.

Furthermore, it is unnecessary to try and prevent all fishing mortality for the remainder of fishing year 2014 as the stock can rebuild if subject to overfishing in 2014 and sufficient measures are in place beginning in 2015. To achieve zero fishing mortality would require closing all fisheries in the Gulf of Maine, including those that do not target groundfish. The impacts of such measures would be substantial and, as a result, such a closure is impracticable and unwarranted to ensure effective cod conservation.

In requesting the emergency action, the Council was not specific in describing measures it recommended to reduce fishing mortality for the remainder of fishing year 2014. We agree that, based on the updated assessment, fishing mortality must be greatly reduced for GOM cod as soon as possible to help ensure that overfishing can be ended and the stock can rebuild. To allow fishing on GOM cod for the rest of this fishing year without any additional measures and under the available annual catch limit (ACL), would reduce the likelihood of ending overfishing and successfully rebuilding the stock in subsequent years. We contemplated making changes to the ACL for the rest of fishing year 2014, which would trigger a quota recall. However, doing so would be administratively complex and a challenge to implement quickly. Given the stage of the fishing year, it would also be challenging to administer a quota recall in an equitable fashion. The Council is developing specifications for the 2015 fishing year (May 1, 2015, to April 30, 2016) in Framework Adjustment 53 that would reduce the GOM cod ACLs based on the 2014 stock assessment update for cod.

We chose time and area closures as the best means to reduce catch for the remainder of fishing year 2014 in light of the objectives stated above. In selecting these areas, we analyzed where the majority of 2010 to mid-calendar year 2014 GOM cod catches have occurred. The basis for our analysis is that fishermen have fished where the stock is located and by selectively closing some of these areas, catch can be reduced and the standing stock protected. These analyses indicated several locations where cod have consistently been taken in commercial and recreational fisheries during this time. Our analysis indicates that while catches were more inshore during 2010–12, a higher proportion of catch occurred east of the year-round WGOM Closure Area in 2013 and thus far in 2014. It is not known if this is a shift in fishing behavior, redistribution

of the GOM cod stock, or some combination of both. It is also not known if effort and the stock may shift back inshore during peak spawning periods yet to come for winter and spring 2015. This redistribution mirrors anecdotal information recently provided by the fishing industry. The areas and times selected for closure, therefore, were informed by these most recent trends of fishing but also provide protection for areas of high catch earlier in the period evaluated.

We also chose measures to reduce fishing mortality on GOM cod based on the potential of effort shifting to other groundfish stocks. We were particularly concerned about potential haddock interactions, as we are undertaking concurrent action to increase the fishing year 2014 commercial haddock catch allowance for the remainder of the year. We kept open areas where the amount of non-cod species catch might be strong but the potential cod catch relatively low. In cases where co-occurrence of cod and other likely target stocks were high, the areas were closed to reduce cod fishing mortality and to discourage intentional targeting of cod or incidental take of cod while fishing for other stocks.

For GOM cod to have a meaningful chance to recover, not only must fishing mortality be controlled, but the complex courtship and spawning process must be protected. To this end, we are also closing areas important to spawning and spawning potential. The spawning-related closure measures are based on information assembled by the Closed Area Technical Team for the Council's Omnibus Habitat Amendment 2, information from the Industry Based Survey, Massachusetts Division of Marine Fisheries research, and scientific literature. Because of difficulty in pinpointing spawning spatially and temporally, we used broad, larger areas for the spawning-related closures. The use of larger areas is expected to provide more protection for spawning activities than would smaller or disaggregated areas. This is because there is strong evidence that pre-spawning courtship and foraging, spawning activities, and post-spawning egress from areas can be substantially impacted by fishing activities and result in high fishery removals. In particular, the focused harvest of spawning aggregations in Atlantic Canada is often cited as a substantial contribution to the cod stock collapse there in the early 1990s. More information on the analyses we performed is available in the EA and not repeated here.

In selecting spawning-related closures, we first examined if areas were

known or likely to be cod spawning or spawning activity related areas. When areas/times were verified, we designated those areas for closure irrespective of how much cod catch had historically occurred in the time/area. Next, we looked for areas that produced a proportionately high cod catch relative to the total cod caught in a given month because there is a strong correlation between high cod catch and spawning activity. Accordingly, those areas that provide high proportional catches, particularly in recent years, were designated for closure.

As another basis for selecting the closed areas, if an area produced moderate catches or had variable catch contributions over time, we evaluated the tradeoff between closing the area for cod mortality reduction and the potential foregone access to other, more abundant stocks. We attempted to strike a balance between ensuring cod mortality would, in fact be reduced, while providing access to other stocks.

The analyses we undertook indicate that by closing areas identified as producing a high proportion of cod catch and/or are involved with cod spawning activities, it may be possible to reduce GOM cod catch by a sizable amount—ranging from 68 to 82 percent for commercial and 73 to 81 percent for recreational catch, depending on which of the years from 2010 to 2014 are included in the analysis. These potential reductions should be viewed with the caveat that they are the result of evaluating how much catches would be reduced had the interim measure closures been in place for 12 months, fishing behaviors remained unchanged, and stock distribution stayed the same. This evaluation does not consider the catch that has already occurred for fishing year 2014, so it is not appropriate to conclude that approximately 75 percent of the ACL will be taken, for example. Any number of these assumptions may change and, as a result, the reductions should be viewed as a potential relative reduction in fishing mortality/catch. In particular, effort may shift to areas not heavily targeted for cod following implementation of these seasonal closures. In any given year, no more than 32 percent of the total commercial and 27 percent of the total recreational cod catch occurred in the areas being left open under this interim action. As a result, it is not possible to precisely quantify the potential magnitude of fishing mortality reduction that will result from the area closures; however, the analysis indicates closing these areas should be effective in reducing GOM cod catch and reducing

overfishing, in lieu of reducing commercial ACL inseason. The closure areas also provide the added benefit protecting fall/winter/spring GOM cod spawning activities.

As previously indicated, implementation of these closure areas will be delayed for 2 weeks so that fixed gear can be removed from the November closure areas. However, on and after the date of publication of this rule, vessels transiting these closed areas must have gear stowed in accordance with regulations found in § 648.2. Trawl vessels may use on-net storage provisions in § 648.2 not available for immediate use that pertain to transiting seasonal closure areas.

Commercial Fishery Trip Limits

This action implements a 200-lb (90.7-kg) GOM cod trip limit for all vessels fishing in fishing year 2014 sectors. This means that sector vessels and common pool vessels are now limited to possessing and landing limit of 200 lb (90.7 kg) of GOM cod per trip regardless of the length of a trip. This does not change the current possession and landing limit for Handgear A and Small Vessel category permitted vessels because they were already subject to a 200-lb (90.7-kg) per trip limit under Framework Adjustment 51 measures.

Commercial Fishery Trip Limit Rationale

The 200-lb (90.7-kg) trip limit is necessary to ensure open-area catch does not result in excessive GOM cod fishing mortality by reducing the incentive to target on this stock in areas that would remain open. We evaluated a trip limit versus reducing the ACL and chose the trip limit because reducing ACLs would be administratively complex and something that could not be done quickly. Without a trip limit, there would be a possibility that if GOM cod occurred in any concentrations not expected, then catch reduction objectives from closed areas would be compromised.

A 200-lb (90.7-kg) limit was chosen based on analysis of trip-level catch data from calendar year 2013, the most recent calendar year available for analysis, which indicates that approximately 75 percent of the trips taken in areas that will remain open in this action caught less than 200 lb (90.7 kg). While the range of these trips above 200 lb (90.7 kg) varies from just over 200 lb (90.7 kg) to upwards of 2,000 lb (90.7 kg), these data suggest that the frequency and magnitude of discards would not be excessive even if fishing behaviors are unchanged. This is particularly true when paired with the

expected mortality reductions provided by the interim measure closed areas. If fishing behavior is changed such that fishermen actively seek to avoid catching GOM cod, the likelihood of regulatory discards should be even lower. Overall, even if discards of GOM cod on individual trips increase somewhat as a result of this trip limit, the overall reduction of fishing mortality of this stock should be greater than if no trip limit was in place.

Approximately 25 percent of sector trips are subject to at-sea monitoring or observation. The remaining 75 percent of GOM sector trips are not monitored at sea. Very few fishermen report discards on their Vessel Trip Reports. However, we are hopeful that fishermen will take measures to avoid catching GOM cod by either avoiding areas of known cod concentration, using selective gear, leaving areas where cod are unexpectedly captured, and, when necessary, reporting cod discards. There are several uncertainties about how effort may shift in response to the closed areas and what GOM cod catch rates may be in the remaining open areas. Trip limits are an essential component to mitigating these uncertainties while attempting to ensure the overarching objectives for GOM cod are not compromised if effort and catches would otherwise be high in open areas. We expect trip limits to effectively dissuade targeting behavior, even with concerns about discards and monitoring. However, our message is clear: Avoid cod, if at all possible.

We expect the Council will put in place 2015 GOM cod catch limits that will constrain operations because of low common pool sector catch limits. Thus, it is likely that sector trip limits will only be necessary until May 1, 2015, as a way to ensure overfishing is reduced for the remainder of the 2014 fishing year. The Council's SSC has recommended 485 mt as an acceptable biological catch (ABC) for the 2015 fishing year.

Commercial Fishery Declaration Changes

This interim rule also prohibits commercial fishing vessels in both the sector program and common pool that declare trips in the GOM Broad Stock Area from fishing in other broad stock areas (i.e., Georges Bank (GB) or Southern New England (SNE)) on the same trip.

Broad Stock Area Declaration Changes Rationale

NMFS, the Council, and Council's Groundfish Oversight Committee have expressed concern that there is a strong

incentive to misreport catch on unobserved trips in situations where catch limits or available annual catch entitlement (ACE) may be constraining. There are retrospective patterns in many groundfish stock assessments that may be the result of unaccounted-for mortality, one source of which may be misreported or unreported catch. To better ensure that accurate apportionment of catch, we are implementing a requirement that restricts trips declared into the GOM Broad Stock Area to fishing in that area only, irrespective of whether the trip is monitored/observed or not. Although recognizing that this measure impedes flexibility previously provided to fish in multiple stock areas on a trip, we have determined that the short-term benefits of this measure are necessary in the context of this interim rule and its objectives to ensure the effectiveness of all of the other measures in this interim rule.

The Council and Committee contemplated a similar requirement restricting vessels to fishing in the inshore GOM area (defined as west of 70° W. longitude) unless an at-sea monitor or observer was onboard. We understood the objective of such a measure was to ensure better catch reporting accuracy and discard estimation for unobserved trips occurring in the inshore GOM area while allowing multiple area trips when the fishing activity was monitored or observed. We considered this approach but were unable to adopt the specific approach discussed by the Committee and Council for two reasons: First, the existing reporting areas are based on broad stock areas (e.g., GOM). We would have to create a new inshore reporting area which would require changes to Vessel Monitoring System (VMS) areas and reporting requirements. Furthermore, new monitoring strata would be required for estimating discards inside and outside this area. This change would have implications for prescribed monitoring coverage levels and funding for the year. Such changes would also extend the development and implementation time of an emergency action and, as a result, were not implemented because of the overarching need to put in place cod conservation measures quickly.

Second, putting in place this type of flexibility can create a bias for observed trips that are randomly selected for observer or at-sea monitoring coverage through the pre-trip notification system (PTNS). We are concerned that the flexibility to fish in multiple areas on a trip provides a strong incentive to wait and undertake a multiple-area trip if

selected for monitoring. This could mean fewer observers/monitors deploy on standard trips which would undermine the reliability of discard rates for unobserved trips that are operating in areas differently than those that are observed.

Because of these concerns, the most expeditious way to improve GOM cod catch apportionment in the context of this interim rule is to restrict fishing activity to the GOM for trips declared into the broad stock area. Vessels may continue to declare into the Inshore and Offshore Georges Bank or Southern New England Broad Stock Areas and fish in both on a trip, provided all other existing declaration and reporting requirements for so doing are satisfied. We will encourage the Council to consider the implications of multiple stock area trips moving forward as long-term GOM cod recovery measures are discussed for Framework Adjustment 53 implementation.

Prohibition on Recreationally Caught GOM Cod

This interim rule extends the current prohibition on possession or landing GOM cod in or from Federal waters by recreational anglers and federally permitted party and charter vessels to the end of the fishing year, April 30, 2015. The prohibition may be extended beyond May 1, 2015, pending further Council discussion and/or agency evaluation of fishing year 2015 accountability measures.

The possession of recreationally caught GOM cod was already in place for September 1, 2014, to April 14, 2015, under the measures implemented for fishing year 2014 (77 FR 22419; April 22, 2014). This rule extends that prohibition until at least April 30, 2015.

Recreational Possession Prohibition Rationale

This change is necessary to minimize additional recreational catch and discard mortality for GOM cod. Marine Recreational Information Program (MRIP) data for May–August 2014 indicates that the fishing year 2014 recreational sub-ACL has already been exceeded, prior to the opening of the scheduled spring fishery. MRIP data through waves 3 and 4 (May–August 2014) indicate a recreational GOM cod catch of approximately 500 mt. The recreational GOM cod sub-ACL for the 2014 fishing year is 486 mt. A prohibition on possession does not preclude recreational fishing in areas not otherwise closed to gear capable of catching cod by this interim rule. However, similar to commercial trip limits, we expect that a prohibition on

retention will dissuade fishing activity in areas where cod are frequently taken in recreational fisheries. As with the commercial fishery, even if discards may increase on some individual trips, overall mortality due to recreational fishing is expected to decrease, particularly since a portion of recreationally captured cod are estimated to survive. Discard survivability may be enhanced further by good handling techniques and through use of baited hooks that better ensure mouth hooking. Preliminary work by several New England fisheries research institutions shows a higher incidence of severe body injury and associated mortality for cod taken with unbaited jig tackle.

Additional measures to reduce GOM cod recreational mortality are anticipated for the May 1, 2015, start date of fishing year 2015, given the 2014 overage and expected reduction in the overall catch limit next year. We will work with the Council as such measures are developed and will either implement interim measures, as needed for fishing year 2015, or will assist in implementing recreational measures through Framework Adjustment 53 rulemaking.

Sector Day Gillnet Limit on Number of Gillnets; Exemption Revocation

This action rescinds a previously issued fishing year 2014 sector exemption (79 FR 23278; April 28, 2014) for the number of gillnets that Day gillnet vessels fishing in the GOM can use. With this exemption rescinded, Day gillnet vessels will be subject to the existing regulation restricting them to using no more than 100 gillnets of 300 feet (91.4 m), or 50 fathoms (91.4 m) in length in the GOM. Of these 100 gillnets, no more than 50 gillnets may be rigged for roundfish (i.e., gillnets that are constructed with floats on the float line and that have no tie-down twine between the float line and the lead line).

Number of Gillnets for Day Gillnet Vessels Exemption Revocation Rationale

We examined all fishing year 2014 issued sector exemptions, seeking to evaluate their potential impact on GOM cod. The Council discussed including exemption review in its emergency action request. Although ultimately, the Council did not ask us to review the possibility of rescinding sector exemptions, we examined which exemptions may be negatively impacting cod through high cod selectivity or disruption to spawning activity. We determined that the closed areas and other management

measures in this rule provide sufficiently robust catch reduction and stock protection measures that, other than the gillnet exemption, no other exemption needed to be modified or revoked for the remainder of the 2014 fishing year.

Day gillnet fishermen leave their nets fishing when they come in and out of port. The 2014 sector exemption allowed them to fish up to 150 nets, all of which could be roundfish nets. In both 2013 and 2014, we reduced this flexibility by removing the exemption when fishing in 30-minute blocks 124 and 125 in May and blocks 132 and 133 in June, because of concerns relating to mortality to GOM cod caused by continuous fishing by gillnets left in the water and the potential to disrupt spawning when cod are caught. In addition to the overall amount of Day gillnet gear in the water, we are also concerned that continuing the exemption could cause barriers of gillnets along the boundaries of closed areas that would otherwise catch cod going into or coming out of the closed areas. As a result, we are revoking this exemption as a discrete and effective measure that could reduce the overall mortality of GOM cod.

We will allow a 2-week window from the date of publication of this rule for Day gillnet vessels to remove excess gear from the GOM Broad Stock Area.

Other Measures Considered But Rejected

In our consideration of what measures would provide catch reduction and stock protection in the context of an interim rule with the objectives stated above, we felt it important that measures must be developed, analyzed, and implemented quickly to be of benefit for the remainder of fishing year 2014 and to provide stop-gap measures while the Council develops Framework Adjustment 53 to address on a long-term basis the updated assessment. This limited the scope and scale of options.

We considered wholesale closure of the GOM; however, we thought that the negative socio-economic impacts were not justified for the conservation return that could be realized for such an action. As indicated in current analyses, it is not necessary to stop all mortality on this stock for it to be rebuilt over time as long as appropriate measures are implemented in 2015 and onward.

We considered requiring selective trawl gear use in conjunction with closed areas. These types of nets have demonstrated an ability to reduce cod catch when properly outfitted and fished. We were concerned that the benefits of requiring such gear would be

diluted due to delays necessary to allow fishermen to comply with this action. In light of this delay and the difficulty in quantifying the amount of reduction in overall GOM cod mortality that would come from such a measure, we determined that costs that fishermen would incur for purchasing or rigging new gear did not justify imposing this requirement as a potentially short-term interim measure.

We constrained our evaluation to modifications of existing measures or things that could be quickly implemented. This was necessary because new concepts and measures would take more time to develop and would potentially delay implementation of any action. For example, changes in VMS require clearance under the Paperwork Reduction Act. Although by itself this is not an insurmountable issue, it would require additional time to complete the required clearances, which would be contrary to the purpose of this action to reduce overfishing of GOM cod as soon as possible. We also started our evaluation by considering what the Council and Committee discussed, including evaluating the alternatives that the Council has initiated for Framework Adjustment 53 because these interim measures should attempt to complement and bolster the potential Council actions. As an interim action, the scope, scale and type of the measures are necessarily different than those the Council may consider and has discussed for fishing year 2015. For example, the Council may choose to make use of catch limits that end overfishing in fishing year 2015 whereas this interim rule was constricted to using closed areas and trip limits as explained above.

We were also concerned about concurrently increasing the GOM haddock catch limits in response to new assessment information for that stock. We considered not increasing haddock catch limits in the face of this action but recognize the desire for fisheries flexibility to target healthy stocks and the need to further mitigate the negative consequences of this action and relatively low overall catch limits for many stocks including GOM haddock in Framework Adjustment 51. We believe the combination of closed areas that will reduce cod and to some extent haddock catch, trip limits, and limitations of available sector annual catch entitlement (ACE) for other stocks will help ensure that cod mortality associated with targeting haddock will not jeopardize the overall objective of this action in reducing cod overfishing while the Council develops longer-term measures in Framework Adjustment 53.

6-Month Renewal of Interim Measures

NMFS' interim authority is available for up to 180 days in an initial action and is open to public comments. After considering public comments, the interim rule may be extended or modified up to an additional 186 days after the date of publication by a subsequent rulemaking, which provides for a full year (12 consecutive months) of interim measures, if necessary. NMFS may renew and modify interim measures on or about March 2015 to provide cod mortality reduction and protection measures for the beginning of the 2015 fishing year that begins May 1, 2015, as needed. Our intent is to work with the Council as it develops measures for Framework Adjustment 53; however, should the Council either not take action or not recommend sufficient measures for fishing year 2015, we may extend these or other interim measures for an additional period not to exceed an additional 186 total days. As examples of measures that could be implemented on May 1, it may be necessary to implement recreational measures for the start of the fishing year or modify closure area locations and times based on more protracted evaluation of spawning information or catch distribution. We are accepting comment on these initial interim measures for consideration on the extension, should one be warranted.

Justification for Interim Action

The Magnuson-Stevens Act authorizes the Secretary to act if (1) the Secretary finds that an emergency involving a fishery exists; or (2) the Secretary finds that interim measures are needed to reduce overfishing in any fishery; or (3) if the Council finds one of those factors exists and requests that the Secretary act. See section 305 of the Magnuson-Stevens Act, 16 U.S.C. 1855(c). Where such circumstances exist, the Secretary may promulgate emergency rules or interim measures "to address the emergency or overfishing" 16 U.S.C. 1855(c)(1) and (2). The Secretary has delegated this authority to NMFS. Further, NMFS has issued guidance defining when "an emergency" involving a fishery exists (62 FR 44421; August 21, 1997). This guidance defines an emergency as a situation that (1) arose from recent, unforeseen events, (2) presents a serious conservation problem in the fishery, and (3) can be addressed through interim emergency regulations for which the immediate benefits outweigh the value of advance notice, public comment, and the deliberative consideration of the impacts on participants to the same extent as would

be expected under the formal rulemaking process. Under the statute and guidance, the rationale for issuing these emergency and interim regulations is as follows: The August 2014 GOM cod assessment update indicates that the stock is overfished, is subject to overfishing, and is at a historically low level of abundance. The measures currently in place for fishing year 2014 may result in substantial overfishing of the stock and compromise the stock's ability to rebuild over the long term if not implemented as soon as possible. This action is necessary to reduce overfishing, consistent with the stated authority in section 305(c) of the Magnuson-Stevens Act.

Both NMFS and the Council agree with the stock assessment update's findings and that the stock is in need of immediate emergency measures to reduce overfishing and protect stock aggregations and spawning activities as a stop-gap while the Council develops longer-term measures necessitated by the updated assessment. Stated more simply, catch must be reduced and when and where cod are caught matters. The Council process would not be able to develop and recommend a framework adjustment, or other management measures, until its November 2014 meeting at earliest and most likely later. NMFS would not be able to consider and implement any such Council recommendations, even if issued directly as a final rule without prior public comment, until late winter or early spring. Based on these considerations, the Council voted 14 for, 3 against, to recommend that NMFS take emergency action as expeditiously as possible on behalf of the Secretary. NMFS stated its support for this request during Council deliberations, as the agency believes GOM cod is in need of immediate and rigorous protection. The Council's request is to use measures to reduce fishing mortality in fishing year 2014 while the Council works on long-term measures for May 1, 2015, implementation through Framework Adjustment 53. Accordingly, under the Magnuson-Stevens Act, NMFS, issues these emergency interim measures to address the need to reduce overfishing and protect the stock of GOM cod more expeditiously than the Council process or standard Administrative Procedure Act (APA) agency rulemaking could achieve.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has made a determination that this interim rule is consistent with the Northeast

Multispecies Fishery Management plan (FMP), section 305(c) and other provisions of the Magnuson-Stevens Act, the APA, and other applicable law.

Section 553 of the APA establishes procedural requirements applicable to rulemaking by Federal agencies. The purpose of these requirements is to ensure public access to the Federal rulemaking process and to give the public adequate notice and opportunity for comment. Pursuant to 5 U.S.C. 553(b)(B) and 5 U.S.C. 553(d)(3), the Assistant Administrator for Fisheries finds good cause to waive the otherwise applicable requirements for both notice and comment rulemaking and a 30-day delay in effectiveness for this temporary rule implementing GOM cod management measures.

The availability of information and need for expedient action makes it impracticable to provide prior notice-and-comment opportunity and a 30-day cooling off period. The updated GOM cod assessment was initially made available in August and peer review was conducted late in that same month. The assessment indicates the GOM cod stock continues to be overfished, subject to substantial overfishing, and is estimated to be the smallest total size in recorded history. Over the course of September, the Council's Plan Development Team and Scientific and Statistical Committee received the results of the assessment and peer-review before providing advice to the Council's Groundfish Oversight Committee on September 24, 2014. In turn, the Committee recommended to the Council that a recommendation for emergency action be forwarded to NMFS. The Council deliberated on the Committee recommendation on October 1, 2014. The Council overwhelmingly agreed that the fishing mortality for GOM cod needed to be reduced as quickly as possible for the remainder of fishing year 2014. The existing catch limits, if left in place with no additional management changes, have the potential to result in fishing at a rate four times the desired fishing mortality for the year. This is substantial overfishing. The temporary rule is designed to implement measures that will decrease fishing mortality and reduce overfishing, shift fishing effort from areas of recent high catches where cod are believed to be aggregated, and to protect cod spawning areas and activities. Reducing catch limits, which would include recalling previously issued sector ACE during the fishing year, would be administratively complex and time consuming. By taking the approach outlined in this temporary rule, NMFS can put in place measures that have the potential to reduce fishing

mortality, as requested by the Council. In the interim between this action and the start of the 2015 fishing year that begins May 1, 2015, the Council will develop and recommend long-term solutions, including potentially lower ACLs, designed to protect and rebuild GOM cod.

These timing-related issues paired with the need to complete analyses and the rulemaking processes as quickly as possible to reduce cod catches and end overfishing make it impracticable to propose GOM cod measures through notice-and-comment rulemaking. During the delay in which measures were developed and implemented, additional and potentially excessive GOM cod fishing mortality was expected to occur. In addition, some empirical data indicate that spawning, as indicated by ripe and running fish, begins in November. To provide protection for the 2014 spawning activities that begin in fall and continue through winter into spring, expediting these emergency measures is necessary.

For the reasons outlined, NMFS finds it impracticable and contrary to the public interest to provide prior opportunity to comment on these GOM cod emergency measures and provide a 30-day delay in implementation. Therefore, there exists good cause to waive both of those requirements.

NMFS has consulted with the Office of Information and Regulatory Affairs (OIRA) and due to the circumstances described above this action is exempt from review under Executive Order 12866.

This interim final rule does not contain policies with Federalism or "takings" implications as those terms are defined in E.O. 13132 and E.O. 12630, respectively.

This interim final rule is exempt from the procedures of the Regulatory Flexibility Act because the rule is issued without opportunity for prior notice and opportunity for public comment.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: November 6, 2014.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

Therefore, NOAA amends 50 CFR part 648 as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. Section 648.2 is amended by:

■ a. Suspending from November 13, 2014 until April 30, 2015, the definition for "Gillnet gear capable of catching multispecies"; and

■ b. Temporarily add from November 13, 2014 until April 30, 2015, a definition for "Gillnet gear capable of catching multispecies (for purposes of the interim action)", in alphabetical order.

The addition reads as follows.

§ 648.2 Definitions.

* * * * *

Gillnet gear capable of catching multispecies (for purposes of the interim action) means all gillnet gear except pelagic gillnet gear specified at § 648.81(o)(2)(ii) and pelagic gillnet gear that is designed to fish for and is used to fish for or catch tunas, swordfish, and sharks.

* * * * *

■ 3. Section 648.10 is amended by adding paragraph (k)(3)(i)(A) and reserved paragraph (k)(3)(i)(B) to read as follows:

§ 648.10 VMS and DAS requirements for vessel owners/operators.

* * * * *

(k) * * *

(3) * * *

(i) * * *

(A) Vessels that notify NMFS of their intended fishing activity in accordance with paragraphs (g), (h), or (k) of this section, must declare one or more NE multispecies broad stock areas, as defined in paragraphs (k)(3)(i) through (iv) of this section, unless otherwise specified in this paragraph (k)(3)(i)(A). If a vessel declares to fish in the GOM Stock Area I as defined in paragraph (k)(3)(i), the vessel is prohibited from fishing outside of the GOM Stock Area I on that trip.

(B) [Reserved]

* * * * *

■ 4. Section 648.14 is amended by:

■ a. Suspending from November 13, 2014 until April 30, 2015, paragraphs (k)(6)(i)(E), (k)(7)(i)(A) and (B), (k)(12)(v)(E) and (F), (k)(13)(i)(D)(1) through (4), (k)(13)(ii)(B) through (D), (k)(14)(viii), and (k)(16)(iii)(A) through (C);

■ b. Revising paragraphs (k)(12)(i) introductory text, (k)(13)(i) introductory text; and

■ c. Temporarily adding from November 13, 2014 until April 30, 2015, paragraphs (k)(6)(i)(H), (k)(7)(i)(H) through (J), (k)(12)(v)(K) and (L), (k)(13)(i)(D)(5) and (6), (k)(13)(ii)(K) through (M), (k)(14)(xii), and (k)(16)(iii)(D) through (F).

The revisions and additions read as follows:

§ 648.14 Prohibitions.

* * * *

(k) * * *

(6) * * *

(i) * * *

(H) Use, set, haul back, fish with, or possess on board a vessel, unless not available for immediate use as defined in § 648.2, or fail to remove, sink gillnet gear and other gillnet gear capable of catching NE multispecies, with the exception of single pelagic gillnets (as described in § 648.81(o)(2)(ii)), in the areas and for the times specified in § 648.80(g)(6)(iii) and (iv), except as provided in § 648.80(g)(6)(iii) and (iv), and § 648.81(o)(2)(ii), or unless otherwise authorized in writing by the Regional Administrator.

* * * *

(7) * * *

(i) * * *

(H) *Seasonal Interim Closure Areas.* Fish for, harvest, possess, or land regulated species in or from the closed areas specified in § 648.81(o)(1), except as provided in § 648.81(o)(2).

(I) Enter, be on a fishing vessel in, or fail to remove gear from the EEZ portion of the areas described in § 648.81(d)(3) through (g)(1), except as provided in § 648.81(d)(4), (e)(3), (g)(2), and (i), and (o)(2).

(J) Fish for, harvest, possess, or land regulated species in or from the closed areas specified in § 648.81(a) through (f) and (o), unless otherwise specified in § 648.81(c)(2)(iii), (i), (o)(2), or as authorized under § 648.85.

* * * *

(12) *SAP restrictions.* (i) It is unlawful for any person to:

* * * *

(v) * * *

(K) If fishing in the Regular B DAS Program specified in § 648.85(b)(6), fail to comply with the landing limits specified in § 648.85(b)(6)(iv)(K).

(L) If fishing under a Regular B DAS in the Regular B DAS Program, fail to comply with the DAS flip requirements of § 648.85(b)(6)(iv)(E) if the vessel harvests and brings on board more than the landing limit for a groundfish stock of concern specified in § 648.85(b)(6)(iv)(K), other groundfish specified under § 648.86, or monkfish under § 648.94.

(13) *Possession and landing restrictions.* (i) It is unlawful for all persons to:

* * * *

(D) * * *

(5) Enter port, while on a NE multispecies trip, in possession of more

than the allowable limit of cod specified in § 648.82(b)(7) or (8); § 648.86(b)(5), unless the vessel is fishing under the cod exemption specified in § 648.86(b)(7); § 648.87(c)(2)(ii)(E); or § 648.88(a)(1).

(6) Fail to declare through VMS an intent to be exempt from the GOM cod trip limit under § 648.86(b)(5), as required under § 648.86(b)(7), or fish north of the exemption line if in possession of more than the GOM cod trip limit specified under § 648.86(b)(5).

(ii) * * *

(K) Possess or land per trip more than the possession or landing limits specified in § 648.86(a), (b), (c), (e), (g), (h), (j), (l), (m), (n), and (o); § 648.82(b)(7) and (8); § 648.85; or § 648.88, if the vessel has been issued a limited access NE multispecies permit or open access NE multispecies permit, as applicable.

(L) Fish for, possess at any time during a trip, or land regulated NE multispecies or ocean pout specified in § 648.86 after using up the vessel's annual DAS allocation or when not participating in the DAS program pursuant to § 648.82, unless otherwise exempted by §§ 648.82(b)(7), 648.87, or 648.89, or allowed pursuant to §§ 648.85(b)(6) or 648.88.

(M) *Atlantic cod.* (1) Enter port, while on a NE multispecies DAS trip, in possession of more than the allowable limit of cod specified in § 648.86(b)(5), unless the vessel is fishing under the cod exemption specified in § 648.86(b)(7).

(2) Enter port, while on a NE multispecies DAS trip, in possession of more than the allowable limit of cod specified in § 648.86(b)(6).

(3) Fail to declare through VMS an intent to be exempt from the GOM cod trip limit under § 648.86(b)(5), as required under § 648.86(b)(7), or fish north of the exemption line if in possession of more than the GOM cod trip limit specified under § 648.86(b)(5).

(14) * * *

(xii) With the exception of GOM cod, discard legal-sized regulated species or ocean pout allocated to sectors pursuant to § 648.87(b)(1)(i), as prohibited by § 648.87(b)(1)(v).

* * * *

(16) * * *

(iii) * * *

(D) If fishing under the recreational or charter/party regulations, fish for or possess cod caught in the GOM Regulated Mesh Area as specified under § 648.89(c)(8), or fail to abide by the appropriate restrictions if transiting with cod on board.

(E) If the vessel has been issued a charter/party permit or is fishing under

charter/party regulations, fail to comply with the requirements specified in § 648.81(o)(2)(iii) when fishing in the areas described in § 648.81(d)(3) through (o)(1) during the time periods specified.

(F) If the vessel is a private recreational or charter/party boat fishing vessel, fail to comply with the GOM cod possession prohibition described in § 648.89(c)(8).

* * * *

■ 5. Section 648.80 is amended by:

■ a. Suspending from November 13, 2014 until April 30, 2015, paragraphs (a)(3)(vi), (a)(4)(iii), and (g)(6)(i) and (ii); and

■ b. Temporarily adding from November 13, 2014 until April 30, 2015, paragraphs (a)(3)(viii), (a)(4)(ix), and (g)(6)(iii) and (iv).

The additions read as follows:

§ 648.80 NE multispecies regulated mesh areas and restrictions on gear and methods of fishing.

* * * *

(a) * * *

(3) * * *

(viii) *Other restrictions and*

exemptions. A vessel is prohibited from fishing in the GOM or GB Exemption Area as defined in paragraph (a)(17) of this section, except if fishing with exempted gear (as defined under this part) or under the exemptions specified in paragraphs (a)(5) through (7), (a)(9) through (16), (a)(18) and (19), (d), (e), (h), and (i) of this section; or if fishing under a NE multispecies DAS; or if fishing on a sector trip; or if fishing under the Small Vessel or Handgear A permit specified in § 648.82(b)(7) and (8), respectively; or if fishing under a Handgear B permit specified in § 648.88(a); or if fishing under the scallop state waters exemptions specified in § 648.54 and paragraph (a)(11) of this section; or if fishing under a scallop DAS in accordance with paragraph (h) of this section; or if fishing pursuant to a NE multispecies open access Charter/Party or Handgear permit specified in § 648.88; or if fishing as a charter/party or private recreational vessel in compliance with § 648.89. Any gear used by a vessel in this area must be authorized under one of these exemptions. Any gear on a vessel that is not authorized under one of these exemptions must not be available for immediate use as defined in § 648.2.

(4) * * *

(ix) *Large-mesh vessels.* When fishing in the GB Regulated Mesh Area, the minimum mesh size for any trawl net, or sink gillnet, and the minimum mesh size for any trawl net, or sink gillnet, when fishing in that portion of the GB

Regulated Mesh Area that lies within the SNE Exemption Area, as described in paragraph (b)(10) of this section, that is not stowed and available for immediate use as defined in § 648.2, on a vessel or used by a vessel fishing under a DAS in the Large-mesh DAS program, specified in § 648.82(b)(7), is 8.5-inch (21.6-cm) diamond or square mesh throughout the entire net. This restriction does not apply to nets or pieces of nets smaller than 3 ft (0.9 m) × 3 ft (0.9 m), (9 sq ft (0.81 sq m)), or to vessels that have not been issued a NE multispecies permit and that are fishing exclusively in state waters.

* * * * *

(g) * * *

(6) * * *

(iii) *Requirements for gillnet gear capable of catching NE multispecies to reduce harbor porpoise takes.* In addition to the requirements for gillnet fishing identified in this section, all persons owning or operating vessels in the EEZ that fish with sink gillnet gear and other gillnet gear capable of catching NE multispecies, with the exception of single pelagic gillnets (as described in § 648.81(o)(2)(ii)), must comply with the applicable provisions of the Harbor Porpoise Take Reduction Plan found in § 229.33 of this title.

(iv) *Requirements for gillnet gear capable of catching NE multispecies to prevent large whale takes.* In addition to the requirements for gillnet fishing identified in this section, all persons owning or operating vessels in the EEZ that fish with sink gillnet gear and other gillnet gear capable of catching NE multispecies, with the exception of single pelagic gillnets (as described in § 648.81(o)(2)(ii)), must comply with the applicable provisions of the Atlantic Large Whale Take Reduction Plan found in § 229.32 of this title.

* * * * *

■ 6. Section 648.81 is amended as follows:

■ a. Suspend from November 13, 2014 until April 30, 2015, paragraphs (d)(1) and (2), (e)(1) and (2), (f)(1) and (2), and (g)(1)(i); and

■ b. Temporarily add from November 13, 2014 until April 30, 2015, paragraphs (d)(3) and (4), (e)(3) and (4), (g)(1)(vii), and (o).

The additions read as follows:

§ 648.81 NE multispecies closed area and measures to protect EFH.

* * * * *

(d) * * *

(3) No fishing vessel or person on a fishing vessel may enter, fish in, or be in, and no fishing gear capable of catching NE multispecies, unless

otherwise allowed in this part, may be in, or on board a vessel in the area known as the Cashes Ledge Closure Area, as defined by straight lines connecting the following points in the order stated, except as specified in paragraphs (d)(4) and (i) of this section (a chart depicting this area is available from the Regional Administrator upon request):

CASHES LEDGE CLOSURE AREA

Point		W.
CL1	43°07'	69°02'
CL2	42°49.5'	68°46'
CL3	42°46.5'	68°50.5'
CL4	42°43.5'	68°58.5'
CL5	42°42.5'	69°17.5'
CL6	42°49.5'	69°26'
CL1	43°07'	69°02'

(4) Unless otherwise restricted under the EFH Closure(s) specified in paragraph (h) of this section, paragraph (d)(3) of this section does not apply to persons aboard fishing vessels or fishing vessels:

(i) That are fishing with or using exempted gear as defined under this part, or in the Midwater Trawl Gear Exempted Fishery as specified under 648.80(d), and excluding pelagic gillnet gear capable of catching NE multispecies, except for vessels fishing with a single pelagic gillnet not longer than 300 ft (91.4 m) and not greater than 6 ft (1.83 m) deep, with a maximum mesh size of 3 inches (7.6 cm), provided:

(A) The net is attached to the boat and fished in the upper two-thirds of the water column;

(B) The net is marked with the owner's name and vessel identification number;

(C) There is no retention of regulated species; and

(D) There is no other gear on board capable of catching NE multispecies; (ii) That are fishing under charter/party or recreational regulations, provided that:

(A) For vessels fishing under charter/party regulations in the Cashes Ledge Closure Area or Western GOM Area Closure, as described under paragraph (d) and (e) of this section, respectively, it has on board a letter of authorization issued by the Regional Administrator, as specified in § 648.89(e)(6);

(B) Fish species managed by the NEFMC or MAFMC that are harvested or possessed by the vessel, are not sold or intended for trade, barter or sale, regardless of where the fish are caught; and

(C) The vessel has no gear other than rod and reel or handline on board and

is fishing for pelagic recreational species; and

(D) The vessel does not use any NE multispecies DAS during the entire period for which the letter of authorization is valid;

(iii) That are fishing with or using scallop dredge gear when fishing under a scallop DAS or when lawfully fishing in the Scallop Dredge Fishery Exemption Area as described in § 648.80(a)(11), provided the vessel does not retain any regulated NE multispecies during a trip, or on any part of a trip; or

(iv) That are fishing in the Raised Footrope Trawl Exempted Whiting Fishery, as specified in § 648.80(a)(15).

(e) * * *

(3) No fishing vessel or person on a fishing vessel may enter, fish in, or be in, and no fishing gear capable of catching NE multispecies, unless otherwise allowed in this part, may be in, or on board a vessel in, the area known as the Western GOM Closure Area, as defined by straight lines connecting the following points in the order stated, except as specified in paragraphs (d)(4) and (i) of this section:

WESTERN GOM CLOSURE AREA ¹

Point	N. lat.	W. long.
WGM1	42°15'	70°15'
WGM2	42°15'	69°55'
WGM3	43°15'	69°55'
WGM4	43°15'	70°15'
WGM1	42°15'	70°15'

¹A chart depicting this area is available from the Regional Administrator upon request.

(4) Unless otherwise restricted under paragraph (h) of this section, paragraph (e)(3) of this section does not apply to fishing vessels that meet the criteria in paragraphs (e)(4) of this section, or consistent with the requirements specified under § 648.80(a)(5).

* * * * *

(g) * * *

(1) * * *

(vii) That meet the criteria in paragraphs (o)(2)(i) or (ii) of this section;

* * * * *

(o) *Seasonal Interim Closure Areas.*

(1) No fishing vessel, recreational or commercial, with gear capable of catching GOM cod, may enter or fish in, the Seasonal Interim Closure Areas, as described in paragraphs (o)(1)(i) through (x) of this section, except as specified in paragraphs (o)(2)(i) through (v) of this section. A chart depicting these areas is available from the Regional Administrator upon request.

(i) From January 1 through January 31, the restrictions specified in this

paragraph (o)(1) apply to Seasonal Interim Closure Area 1, which is defined by the following points, connected in the order listed by straight lines, and bounded on the west by the coastline of Massachusetts:

SEASONAL INTERIM CLOSURE AREA 1
[January 1–January 31]

Point	Latitude	Longitude
JAN 1 ..	42°30' N	(¹)
JAN 2 ..	42°30' N	70°30' W
JAN 3 ..	43°00' N	70°30' W
JAN 4 ..	43°00' N	70°00' W
JAN 5 ..	42°15' N	70°00' W
JAN 6 ..	42°15' N	70°30' W
JAN 7 ..	42°00' N	70°30' W
JAN 8 ..	42°00' N	(²)

¹ The intersection of 42°30' N latitude and the Massachusetts coastline.

² The intersection of 42°00' N latitude and the Massachusetts coastline.

(ii) From February 1 through February 28, the restrictions specified in this paragraph (o)(1) apply to Seasonal Interim Closure Area 2, which is defined by the following points, connected in the order listed by straight lines, and bounded on the west by the coastline of Massachusetts:

SEASONAL INTERIM CLOSURE AREA 2
[February 1–February 28]

Point	Latitude	Longitude
FEB 1 ..	42°30' N	(¹)
FEB 2 ..	42°30' N	70°00' W
FEB 3 ..	43°00' N	70°00' W
FEB 4 ..	43°00' N	69°30' W
FEB 5 ..	42°30' N	69°30' W
FEB 6 ..	42°30' N	70°00' W
FEB 7 ..	42°15' N	70°00' W
FEB 8 ..	42°15' N	70°30' W
FEB 9 ..	42°00' N	70°30' W
FEB 10 ..	42°00' N	(²)

¹ The intersection of 42°30' N latitude and the Massachusetts coastline.

² The intersection of 42°00' N latitude and the Massachusetts coastline.

(iii) From March 1–March 31, the restrictions specified in this paragraph (o)(1) apply to Seasonal Interim Closure Area 3, which is defined by the following points, connected in the order listed by straight lines, and bounded on the west by the coastline of Massachusetts and New Hampshire:

SEASONAL INTERIM CLOSURE AREA 3
[March 1–March 31]

Point	Latitude	Longitude
MAR 1	43°00' N	(¹)
MAR 2	43°00' N	70°00' W
MAR 3	43°30' N	70°00' W
MAR 4	43°30' N	69°30' W

SEASONAL INTERIM CLOSURE AREA 3—Continued
[March 1–March 31]

Point	Latitude	Longitude
MAR 5	42°30' N	69°30' W
MAR 6	42°30' W	70°00' W
MAR 7	42°15' N	70°00' W
MAR 8	42°15' N	70°30' W
MAR 9	42°30' N	70°30' W
MAR 10	42°30' N	(²)

¹ The intersection of 43°00' N latitude and the New Hampshire coastline.

² The intersection of 42°30' N latitude and the Massachusetts coastline.

(iv) From April 1–April 30, the restrictions specified in this paragraph (o)(1) apply to Seasonal Interim Closure Area 4, which is defined by the following points, connected in the order listed by straight lines, and bounded on the west by the coastline of Massachusetts and New Hampshire:

SEASONAL INTERIM CLOSURE AREA 4
[April 1–April 30]

Point	Latitude	Longitude
MAR 1	43°00' N	(¹)
MAR 2	43°00' N	70°00' W
MAR 3	43°30' N	70°00' W
MAR 4	43°30' N	69°30' W
MAR 5	43°00' N	69°30' W
MAR 6	43°00' N	70°00' W
MAR 7	42°15' N	70°00' W
MAR 8	42°15' N	70°30' W
MAR 9	42°00' N	70°30' W
MAR 10	42°00' N	(²)

¹ The intersection of 43°00' N latitude and the New Hampshire coastline.

² The intersection of 42°00' N latitude and the Massachusetts coastline.

(v) From May 1–May 30, the restrictions specified in this paragraph (o)(1) apply to Seasonal Interim Closure Area 5, which is defined by the following points, connected in the order listed by straight lines, and bounded on the west by the coastline of the United States:

SEASONAL INTERIM CLOSURE AREA 5
[May 1–May 30]

Point	Latitude	Longitude
MAY 1	43°30' N	(¹)
MAY 2	43°30' N	70°00' W
MAY 3	42°15' N	70°00' W
MAY 4	42°15' N	70°30' W
MAY 5	42°00' N	70°30' W
MAY 6	42°00' N	(²)

¹ The intersection of 43°30' N latitude and the Maine coastline.

² The intersection of 42°00' N latitude and the Massachusetts coastline.

(vi) From June 1–June 30, the restrictions specified in this paragraph

(o)(1) apply to Seasonal Interim Closure Area 6, which is defined by the following points, connected in the order listed by straight lines, and bounded on the west by the coastline of the United States:

SEASONAL INTERIM CLOSURE AREA 6
[June 1–June 30]

Point	Latitude	Longitude
JUN 1 ..	(¹)	70°30' W
JUN 2 ..	43°00' N	70°30' W
JUN 3 ..	43°00' N	70°00' W
JUN 4 ..	42°15' N	70°00' W
JUN 5 ..	42°15' N	70°30' W
JUN 6 ..	42°30' N	70°30' W
JUN 7 ..	42°30' N	(²)

¹ The intersection of 70°00' W longitude and the Maine coastline.

² The intersection of 42°30' N latitude and the Massachusetts coastline.

(vii) From July 1–August 30, the restrictions specified in this paragraph (o)(1) apply to Seasonal Interim Closure Area 7, which is defined by the following points, connected in the order listed by straight lines:

SEASONAL INTERIM CLOSURE AREA 7
[July 1–August 30]

Point	Latitude	Longitude
JUL 1 ..	43°00' N	70°30' W
JUL 2 ..	43°00' N	70°00' W
JUL 3 ..	43°30' N	70°00' W
JUL 4 ..	43°30' N	69°30' W
JUL 5 ..	43°00' N	69°30' W
JUL 6 ..	43°00' N	70°00' W
JUL 7 ..	42°15' N	70°00' W
JUL 8 ..	42°15' N	70°30' W
JUL 9 ..	43°00' N	70°30' W

(viii) From September 1–October 31, the restrictions specified in this paragraph (o)(1) apply to Seasonal Interim Closure Area 8, which is defined by the following points, connected in the order listed by straight lines:

SEASONAL INTERIM CLOSURE AREA 8
[September 1–October 31]

Point	Latitude	Longitude
JUL 1 ..	43°00' N	70°30' W
JUL 2 ..	43°00' N	70°00' W
JUL 3 ..	42°15' N	70°00' W
JUL 4 ..	42°15' N	70°30' W
JUL 5 ..	43°00' N	70°30' W

(ix) From November 1–November 30, the restrictions specified in this paragraph (o)(1) apply to Seasonal Interim Closure Area 9, which is defined by the following points, connected in the order listed by straight lines, and bounded on the west by the

coastlines of Massachusetts and New Hampshire:

SEASONAL INTERIM CLOSURE AREA 9
[November 1–November 30]

Point	Latitude	Longitude
NOV 1	43°00' N	(1)
NOV 2	43°00' N	70°00' W
NOV 3	42°15' N	70°00' W
NOV 4	42°15' N	70°30' W
NOV 5	42°00' N	70°30' W
NOV 6	42°00' N	MA coast

¹ The intersection of 43°00' N latitude and the New Hampshire coastline.

² The intersection of 42°00' N latitude and the Massachusetts coastline.

(x) From December 1–December 31, the restrictions specified in this paragraph (o)(1) apply to Seasonal Interim Closure Area 9, which is defined by the following points, connected in the order listed by straight lines, and bounded on the west by the coastline of Massachusetts:

SEASONAL INTERIM CLOSURE AREA 10
[December 1–December 31]

Point	Latitude	Longitude
DEC 1	42°30' N	(1)
DEC 2	42°30' N	70°00' W
DEC 3	42°00' N	70°00' W
DEC 4	42°00' N	(2)

¹ The intersection of 42°30' N latitude and the Massachusetts coastline.

² The intersection of 42°00' N latitude and the Kingston, Massachusetts (mainland) coastline.

(2) Paragraph (o)(1) of this section does not apply to persons aboard fishing vessels or fishing vessels:

(i) That have not been issued a Federal multispecies permit and that are fishing exclusively in state waters;

(ii) That are fishing with or using exempted gear as defined under this part, or in the Midwater Trawl Gear Exempted Fishery as specified under 648.80(d), and excluding pelagic gillnet gear capable of catching NE multispecies, except for vessels fishing with a single pelagic gillnet not longer than 300 ft (91.4 m) and not greater than 6 ft (1.83 m) deep, with a maximum mesh size of 3 inches (7.6 cm), provided:

(A) The net is attached to the boat and fished in the upper two-thirds of the water column;

(B) The net is marked with the owner's name and vessel identification number;

(C) There is no retention of regulated species; and

(D) There is no other gear on board capable of catching NE multispecies;

(iii) That are fishing with or using scallop dredge gear when fishing under a scallop DAS or when lawfully fishing in the Scallop Dredge Fishery Exemption Area as described in § 648.80(a)(11), provided the vessel does not retain any regulated NE multispecies during a trip, or on any part of a trip; or

(iv) That are fishing in the Raised Footrope Trawl Exempted Whiting Fishery, as specified in § 648.80(a)(15).

(v) That are transiting through the Seasonal Interim Closure Areas described in paragraph (o)(1) of this section, provided that gear is not available for immediate use as defined in § 648.2.

■ 7. Section 648.82 is amended as follows:

■ a. Suspend from November 13, 2014 until April 30, 2015, paragraphs (b)(5) and (6); and

■ b. Temporarily add from November 13, 2014 until April 30, 2015, paragraphs (b)(7) and (8)

The additions read as follows:

§ 648.82 Effort-control program for NE multispecies limited access vessels.

* * * * *

(b) * * *

(7) *Small Vessel category*—(i) *DAS allocation*. A vessel qualified and electing to fish under the Small Vessel category may retain up to 300 lb (136.1 kg) of cod, haddock, and yellowtail flounder, combined, and one Atlantic halibut per trip, without being subject to DAS restrictions, and the daily possession limits specified for other regulated species and ocean pout, as specified at § 648.86, unless otherwise specified in this paragraph (b)(7). If the vessel elects to fish in the GOM Regulated Mesh Area, as defined at § 648.80(a)(1), the vessel may not possess or retain more than 200 lb (90.7 kg) of cod for the entire trip. If the vessel elects to fish south of the GOM Regulated Mesh Area, as defined at § 648.80(a)(1), the vessel may retain up to 300 lb (136.1 kg) of cod. Any vessel may elect to switch into the Small Vessel category, as provided in § 648.4(a)(1)(i)(2), if the vessel meets or complies with the following:

(A) The vessel is 30 ft (9.1 m) or less in length overall, as determined by measuring along a horizontal line drawn from a perpendicular raised from the outside of the most forward portion of the stem of the vessel to a perpendicular raised from the after most portion of the stern.

(B) If construction of the vessel was begun after May 1, 1994, the vessel must be constructed such that the quotient of

the length overall divided by the beam is not less than 2.5.

(C) Acceptable verification for vessels 20 ft (6.1 m) or less in length shall be USCG documentation or state registration papers. For vessels over 20 ft (6.1 m) in length overall, the measurement of length must be verified in writing by a qualified marine surveyor, or the builder, based on the vessel's construction plans, or by other means determined acceptable by the Regional Administrator. A copy of the verification must accompany an application for a NE multispecies permit.

(D) Adjustments to the Small Vessel category requirements, including changes to the length requirement, if required to meet fishing mortality goals, may be made by the Regional Administrator following framework procedures of § 648.90.

(ii) [Reserved]

(8) *Handgear A category*. A vessel qualified and electing to fish under the Handgear A category, as described in § 648.4(a)(1)(i)(A), may retain up to 300 lb (135 kg) of cod, per trip, one Atlantic halibut and the daily possession limit for other regulated species and ocean pout, as specified under § 648.86, unless otherwise specified in this paragraph (b)(8). If the vessel elects to fish in the GOM Regulated Mesh Area, as defined at § 648.80(a)(1), the vessel may not possess or retain more than 200 lb (90.7 kg) of cod for the entire trip. If the vessel elects to fish south of the GOM Regulated Mesh Area, as defined at § 648.80(a)(1), the vessel may retain up to 300 lb (136.1 kg) of cod. If the GB cod trip limit applicable to a vessel fishing under a NE multispecies DAS permit, as specified in § 648.86(b)(6) is reduced below 300 lb (135 kg) per DAS by NMFS, the cod trip limit specified in this paragraph (b)(8) shall be adjusted to be the same as the applicable cod trip limit specified for NE multispecies DAS permits. For example, if the GB cod trip limit for NE multispecies DAS vessels was reduced to 250 lb (113.4 kg) per DAS, then the cod trip limit for a vessel issued a Handgear A category permit that is fishing outside of the GOM Regulated Mesh Area would also be reduced to 250 lb (113.4 kg). Qualified vessels electing to fish under the Handgear A category are subject to the following restrictions:

(i) The vessel must not use or possess on board gear other than handgear while in possession of, fishing for, or landing NE multispecies, and must have at least one standard tote on board.

(ii) A vessel may not fish for, possess, or land regulated species from March 1 through March 20 of each year.

(iii) Tub-trawls must be hand-hauled only, with a maximum of 250 hooks.

(iv) Declaration. For any such vessel that is not required to use VMS pursuant to § 648.10(b)(4), to fish for GB cod south of the GOM Regulated Mesh Area, as defined at § 648.80(a)(1), a vessel owner or operator must obtain, and retain on board, a letter of authorization from the Regional Administrator stating an intent to fish south of the GOM Regulated Mesh Area and may not fish in any other area for a minimum of 7 consecutive days from the effective date of the letter of authorization. For any such vessel that is required, or elects, to use VMS pursuant to § 648.10(b)(4), to fish for GB cod south of the GOM Regulated Mesh Area, as defined at § 648.80(a)(1), a vessel owner or operator must declare an intent to fish south of the GOM Regulated Mesh Area on each trip through the VMS prior to leaving port, in accordance with instructions provided by the Regional Administrator. Such vessels may transit the GOM Regulated Mesh Area, as defined at § 648.80(a)(1), provided that their gear is not available for immediate use as defined in § 648.2.

* * * * *

■ 8. Section 648.85 is amended as follows:

- a. Suspend from November 13, 2014 until April 30, 2015, paragraph (b)(6)(iv)(D); and
- b. Temporarily add from November 13, 2014 until April 30, 2015, paragraph (b)(6)(iv)(K).

The addition reads as follows:

§ 648.85 Special Management Programs.

* * * * *

- (b) * * *
- (6) * * *
- (iv) * * *

(K) *Landing limits.* Unless otherwise specified in this paragraph (b)(6)(iv)(K), or restricted pursuant to § 648.86, a NE multispecies vessel fishing in the Regular B DAS Program described in this paragraph (b)(6), and fishing under a Regular B DAS, may not land more than 100 lb (45.5 kg) per DAS, or any part of a DAS, up to a maximum of 1,000 lb (454 kg) per trip, of any of the following species/stocks from the areas specified in paragraph (b)(6)(v) of this section: Cod, American plaice, witch flounder, SNE/MA winter flounder, and GB yellowtail flounder; and may not land more than 25 lb (11.3 kg) per DAS, or any part of a DAS, up to a maximum of 250 lb (113 kg) per trip of CC/GOM yellowtail flounder. If the vessel elects to fish in the GOM Regulated Mesh Area, as defined at § 648.80(a)(1), the

vessel may not possess or retain more than 200 lb (90.7 kg) of cod for the entire trip. In addition, trawl vessels, which are required to fish with a haddock separator trawl, as specified in paragraph (a)(3)(iii)(A) of this section, or a Ruhle trawl, as specified in paragraph (b)(6)(iv)(J) of this section, and other gear that may be required in order to reduce catches of stocks of concern as described in paragraph (b)(6)(iv)(J) of this section, are restricted to the trip limits specified in paragraph (e) of this section.

■ 9. Section 648.86 is amended as follows:

- a. Suspend from November 13, 2014 until April 30, 2015, paragraphs (b)(1) through (4); and
- b. Temporarily add from November 13, 2014 until April 30, 2015, paragraphs (b)(5) through (7).

The additions read as follows:

§ 648.86 NE Multispecies possession restrictions.

* * * * *

(b) * * *

(5) *GOM cod landing and possession limit.* Except as provided in paragraph (b)(7) of this section, or unless otherwise restricted under § 648.85, a vessel fishing under a NE multispecies limited access permit, including a vessel issued a monkfish limited access permit and fishing under the monkfish Category C or D permit provisions, may possess or land up to 200 lb (90.7 kg) of GOM cod per trip, provided that it complies with this paragraph (b)(5). Cod on board a vessel subject to this landing limit must be separated from other species of fish and stored so as to be readily available for inspection.

(i) *Declaration.* A limited access multispecies vessel that fishes or intends to fish on a NE multispecies trip in the GOM Regulated Mesh Area, defined in § 648.80(a)(1), must declare its intention to do so through the VMS or IVR, and is prohibited from fishing outside of this area for the remainder of the trip, as specified in § 648.10(k)(3)(i)(1).

(ii) [Reserved]

(6) *GB cod landing and maximum possession limits.* Unless otherwise restricted under § 648.85, a vessel fishing under a NE multispecies DAS permit, including a vessel issued a monkfish limited access permit and fishing under the monkfish Category C or D permit provisions, may land up to 2,000 lb (907.2 kg) of cod per DAS, or part of a DAS, up to 20,000 lb (9,072 kg) provided it complies with the requirements specified in paragraph (b)(7) of this section.

(7) *Exemption.* A NE multispecies limited access vessel fishing under a NE multispecies DAS is exempt from the landing limit described in paragraph (b)(5) of this section when fishing south of the GOM Regulated Mesh Area, defined in § 648.80(a)(1), provided that, when fishing under the common pool fishery, the vessel complies with the requirement of this paragraph (b)(7).

(i) *Declaration.* With the exception of a vessel declared into the U.S./Canada Management Area, as described in § 648.85(a)(3)(ii), a sector vessel, or a common pool vessel that fishes or intends to fish under a NE multispecies DAS south of the line described in paragraph (b)(7) of this section under the cod trip limits described in paragraph (b)(6) of this section, must, prior to leaving port, declare its intention to do so through the VMS, in accordance with instructions to be provided by the Regional Administrator. In lieu of a VMS declaration, the Regional Administrator may authorize such vessels to obtain a letter of authorization. If a letter of authorization is required, such vessel may not fish north of the exemption area for a minimum of 7 consecutive days (when fishing under the multispecies DAS program), and must carry the letter of authorization on board.

(ii) A NE multispecies limited access vessel exempt from the GOM cod landing limit pursuant to paragraph (b)(7)(i) of this section may not fish north of the line specified in paragraph (b)(7) of this section for the duration of the trip, but may transit the GOM Regulated Mesh Area, provided that its gear is unless not available for immediate use as defined in § 648.2.

* * * * *

■ 10. Section 648.87 is amended as follows:

- a. Suspend from November 13, 2014 until April 30, 2015, paragraphs (b)(1)(v)(A), (b)(1)(ix), (c)(2)(i), and (c)(2)(ii)(A) and (B); and
- b. Temporarily add from November 13, 2014 until April 30, 2015, paragraphs (b)(1)(v)(C), (b)(1)(x), (c)(2)(ii)(E) and (F), and (c)(2)(iii).

The additions read as follows:

§ 648.87 Sector allocation.

* * * * *

- (b) * * *
- (1) * * *
- (v) * * *

(C) *Discards.* Except for GOM cod, a sector vessel may not discard any legal-sized regulated species or ocean pout allocated to sectors pursuant to paragraph (b)(1)(i) of this section, unless otherwise required pursuant to

§ 648.86(l). For GOM cod, a sector vessel must discard all GOM cod that is in excess of 200 lb (90.7 kg) when fishing on a groundfish trip. Discards of undersized regulated species or ocean pout, as well as discards of GOM cod that exceed the 200 lb (90.7 kg) trip limit, by a sector vessel must be reported to NMFS consistent with the reporting requirements specified in paragraph (b)(1)(vi) of this section. Discards shall not be included in the information used to calculate a vessel's PSC, as described in § 648.87(b)(1)(i)(E), but shall be counted against a sector's ACE for each NE multispecies stock allocated to a sector.

* * * * *

(x) *Trip limits.* With the exception of the GOM cod trip limit at § 648.86(b)(5), the Atlantic halibut trip limit at § 648.86(c), and the stocks listed in § 648.86(1), a sector vessel is not limited in the amount of allocated NE multispecies stocks that can be harvested on a particular fishing trip, unless otherwise specified in the operations plan.

(c) * * *

(2) * * *

(ii) * * *

(E) Trip limits on NE multispecies stocks for which a sector receives an allocation of ACE pursuant to paragraph (b)(1)(i) of this section (i.e., all stocks except Atlantic halibut, ocean pout, windowpane flounder, and Atlantic wolffish), unless otherwise specified § 648.86(b)(5) and paragraph (b)(1)(x) of this section.

(F) The GB Seasonal Closed Area specified in § 648.81(g).

(iii) *Regulations that may not be exempted for sector participants.* The Regional Administrator may not exempt participants in a sector from the following Federal fishing regulations: Specific time and areas within the NE multispecies year-round closure areas; permitting restrictions (e.g., vessel upgrades, etc.); gear restrictions designed to minimize habitat impacts (e.g., roller gear restrictions, etc.); reporting requirements; and AMs specified at § 648.90(a)(5)(i)(D). For the purposes of paragraph (c)(2)(i) of this section, the DAS reporting requirements specified at § 648.82; the SAP-specific reporting requirements specified at § 648.85; and the reporting requirements associated with a dockside monitoring program are not considered reporting requirements, and the Regional Administrator may exempt sector participants from these requirements as part of the approval of yearly operations plans. For the purpose of paragraph (c)(2)(i) of this section, the Regional

Administrator may not grant sector participants exemptions from the NE multispecies year-round closure areas defined as Essential Fish Habitat Closure Areas as defined at § 648.81(h); the Fippennies Ledge Area as defined in paragraph (c)(2)(i)(A) of this section; Closed Area I and Closed Area II, as defined at § 648.81(a) and (b), respectively, during the period February 16 through April 30; and the Western GOM Closure Area, as defined at § 648.81(e), where it overlaps with any Sector Rolling Closure Areas, as defined at § 648.81(o)(2)(vi). This list may be modified through a framework adjustment, as specified in § 648.90.

(A) *Fippennies Ledge Area.* The Fippennies Ledge Area is bounded by the following coordinates, connected by straight lines in the order listed:

FIPPENNIES LEDGE AREA

Point	N. Latitude	W. Longitude
1	42°50.0'	69°17.0'
2	42°44.0'	69°14.0'
3	42°44.0'	69°18.0'
4	42°50.0'	69°21.0'

(B) [Reserved]

* * * * *

■ 11. Section 648.88 is amended as follows:

■ a. Suspend from November 13, 2014 until April 30, 2015, paragraph (a)(1); and

■ b. Temporarily add from November 13, 2014 until April 30, 2015, paragraph (a)(3).

The addition reads as follows:

§ 648.88 Multispecies open access permit restrictions.

(a) * * *

(3) The vessel may possess and land up to 75 lb (90.7 kg) of cod, and up to the landing and possession limit restrictions for other NE multispecies specified in § 648.86, provided the vessel complies with the restrictions specified in paragraph (a)(2) of this section. If either the GOM or GB cod trip limit applicable to a vessel fishing under a NE multispecies DAS permit, as specified in § 648.86(b)(5) and (6), respectively, is adjusted by NMFS, the cod trip limit specified in this paragraph (a)(1) shall be adjusted proportionally (rounded up to the nearest 25 lb (11.3 kg)). For example, if the GOM cod trip limit specified at § 648.86(b)(5) doubled, then the cod trip limit for the Handgear B category fishing in the GOM Regulated Mesh Area would also double to 150 lb (68 kg).

* * * * *

■ 12. Section 648.89 is amended as follows:

■ a. Suspend from November 13, 2014 until April 30, 2015, paragraphs (b)(3), (c)(1) and (2), and (e)(1) through (3); and

■ b. Temporarily add from November 13, 2014 until April 30, 2015, paragraphs (c)(8) and (e)(4) through (6).

The additions as follows:

§ 648.89 Recreational and charter/party vessel restrictions.

* * * * *

(c) * * *

(8) *Private recreational and charter/party vessels.* (i) Unless otherwise restricted in this paragraph (c)(2), each person on a private recreational vessel may possess no more than 10 cod per day in, or harvested from, the EEZ, and no person on a charter/party vessel may possess more than 10 cod per day. When fishing in the GOM Regulated Mesh Area defined in § 648.80(a)(1), unless otherwise restricted by the GOM Seasonal Interim Closure Areas specified under § 648.81(o), charter and party vessels fishing under this part, and recreational vessels fishing in the EEZ, may not fish for or possess GOM cod.

(ii) For purposes of counting fish, fillets will be converted to whole fish at the place of landing by dividing the number of fillets by two. If fish are filleted into a single (butterfly) fillet, such fillet shall be deemed to be from one whole fish.

(iii) Cod harvested by charter/party vessels, or recreational fishing vessels in or from the EEZ, with more than one person aboard may be pooled in one or more containers. If there is a violation of the possession limit on board a vessel carrying more than one person, the violation shall be deemed to have been committed by the owner or operator of the vessel.

(iv) Private recreational, and charter and party vessels in possession of cod caught outside the GOM Regulated Mesh Area may transit the GOM area, provided all bait and hooks are removed from fishing rods and any cod on board has been gutted and stored.

* * * * *

(e) * * *

(4) *GOM Closed Areas.* Unless otherwise specified in this paragraph (e)(3), a vessel fishing under charter/party regulations may not fish in the GOM closed areas specified at § 648.81(d)(3), (e)(3), and (o)(1) during the time periods specified in those paragraphs, unless the vessel has on board a valid letter of authorization issued by the Regional Administrator pursuant to § 648.81(d)(4) of this section. The conditions and restrictions

of the letter of authorization must be complied with for the rest of the fishing year, beginning with the start of the participation period of the letter of authorization. A vessel fishing under charter/party regulations may not fish in the GOM Cod Spawning Protection Area specified at § 648.81(n)(1) or the GOM Seasonal Interim Closure Areas at § 648.81(o)(1)(i) through (x) during the time periods specified in that paragraph, unless the vessel complies with the requirements specified at § 648.81(n)(2)(iii).

(5) *Nantucket Lightship Closed Area.* A vessel fishing under the charter/party regulations may not fish in the Nantucket Lightship Closed Area specified in § 648.81(c)(1) unless the vessel has on board a letter of authorization issued by the Regional Administrator pursuant to paragraph (e)(6) of this section.

(6) *Letters of authorization.* To obtain either of the letters of authorization specified in paragraphs (e)(4) and (5) of this section, a vessel owner must request a letter from the Greater Atlantic Regional Fisheries Office of NMFS, either in writing or by phone (see Table 1 to 50 CFR 600.502). As a condition of these letters of authorization, the vessel owner must agree to the following:

(i) The letter of authorization must be carried on board the vessel during the period of participation;

(ii) Fish species managed by the NEFMC or MAFMC that are harvested or possessed by the vessel, are not sold or intended for trade, barter or sale, regardless of where the fish are caught;

(iii) The vessel has no gear other than rod and reel or handline gear on board; and

(iv) For the GOM charter/party closed area exemption only, the vessel may not fish on a sector trip, under a NE multispecies DAS, or under the provisions of the NE multispecies Small Vessel Category or Handgear A or Handgear B permit categories, as specified at § 648.82, during the period of participation.

* * * * *

[FR Doc. 2014–26844 Filed 11–10–14; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 130925836–4174–02]

RIN 0648–XD610

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Vessels Using Pot Gear in the Central Regulatory Area of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by vessels using pot gear in the Central Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the 2014 Pacific cod total allowable catch (TAC) apportioned to vessels using pot gear in the Central Regulatory Area of the GOA.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), November 10, 2014, through 2400 hours, A.l.t., December 31, 2014.

FOR FURTHER INFORMATION CONTACT: Obren Davis, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679. Regulations governing sideboard protections for GOA groundfish fisheries appear at subpart B of 50 CFR part 680.

The 2014 Pacific cod TAC apportioned to vessels using pot gear in the Central Regulatory Area of the GOA is 11,352 metric tons (mt), as established by the final 2014 and 2015 harvest specifications for groundfish of the GOA (79 FR 12890, March 6, 2014) and one reallocation (79 FR 64334, October 29, 2014).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator) has

determined that the 2014 Pacific cod TAC apportioned to vessels using pot gear in the Central Regulatory Area of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 11,832 mt and is setting aside the remaining 10 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by vessels using pot gear in the Central Regulatory Area of the GOA. After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the directed fishing closure of Pacific cod for vessels using pot gear in the Central Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of November 6, 2014.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 7, 2014.

Emily H. Menashes,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2014–26865 Filed 11–7–14; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register

Vol. 79, No. 219

Thursday, November 13, 2014

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 875

RIN 3206-AN05

Federal Long Term Care Insurance Program Eligibility Changes

AGENCY: U.S. Office of Personnel Management.

ACTION: Proposed rule.

SUMMARY: The United States Office of Personnel Management (OPM) is proposing to amend the Federal Long Term Care Insurance Program (FLTCIP) regulation to expand eligibility to apply for coverage under the Program. Under the proposed regulation, the definition of “qualified relative” is expanded to cover all individuals who are domestic partners (both same-sex and opposite-sex) of Federal and U.S. Postal Service employees, annuitants, members of the uniformed services, and retired members of the uniformed services. In addition, the proposed regulation provides that adult children of domestic partners will be considered one of the types of individuals comprising the statutory term “qualified relative” who may apply for FLTCIP coverage.

DATES: Comments are due on or before January 12, 2015.

ADDRESSES: Send written comments to Ronald Brown, Policy Analyst, Planning & Policy Analysis, Office of Personnel Management, 1900 E Street NW., Washington, DC 20415-9700; or deliver to OPM, Room 2309, 1900 E Street NW., Washington, DC; or FAX to (202) 606-0636. Comments may also be sent through the Federal eRulemaking Portal at: <http://www.regulations.gov>. All submissions received through the Portal must include the agency name and docket number or the Regulation Identifier Number (RIN) for this rulemaking.

FOR FURTHER INFORMATION CONTACT: Ronald Brown, Policy Analyst, (202) 606-0004, or by email to Ronald.Brown@opm.gov.

SUPPLEMENTARY INFORMATION: In support of the President’s Memoranda of June 17, 2009 and June 2, 2010, concerning Federal Benefits and Non-Discrimination, OPM has identified certain benefits under FLTCIP that may be extended to additional individuals consistent with existing law, whose relationship to the workforce member is considered to constitute a family relationship. The proposed regulation enhances the ability of Federal agencies to provide for the needs of an increasingly diverse workforce. OPM changed its regulation on June 1, 2010 to allow same-sex domestic partners of employees and annuitants to apply for FLTCIP coverage as a qualified relative. OPM now proposes to expand the term “qualified relative” to include all individuals who are domestic partners (both same-sex and opposite-sex) of employees, annuitants, members of the uniformed services and retired members of the uniformed services. In addition, OPM’s June 1, 2010 regulation did not include same-sex domestic partners of members of the uniformed services. This proposed regulation includes domestic partners, both same-sex and opposite-sex, of members and retired members of the uniformed services.

Additionally, just as is currently required for same-sex domestic partners, newly eligible individuals (both same-sex and opposite-sex) will be required to provide documentation to establish that they meet the regulatory criteria for domestic partners.

Finally, OPM has determined that eligibility may be extended to adult children of domestic partners by defining the term “stepchild,” which is one of the types of individuals comprising the statutory term “qualified relative,” to include the child of a domestic partner. The definition of “stepchild” set forth in this proposed regulation appropriately encompasses and reflects the variety of parent-child relationships that exist today.

The proposed changes and clarifications are:

Changes:

(1) We propose to expand the definition of “qualified relative” under 5 U.S.C. 9001(5)(D) to include both same-sex and opposite sex domestic partners of Federal and U.S. Postal Service employees and annuitants and members and retired members of the uniformed services. This revision can be

found in section 875.101 and 875.213 of the proposed rule.

(2) We propose to expand the definition of “qualified relative” to include adult children of domestic partners of Federal and U.S. Postal Service employees and annuitants, and members and retired members of the uniformed services consistent with Presidential Memoranda issued on June 17, 2009 and June 2, 2010. This revision can be found in section 875.101 of the proposed rule.

(3) We propose that the workforce member or his or her domestic partner must provide notice to the employing office if at any time between the time of application and the time coverage is scheduled to go into effect, any of the conditions for a domestic partnership are no longer met, in which case a domestic partnership is deemed terminated. Such notification must be made as soon as possible, but in no event later than thirty calendar days after such conditions are no longer met. This change can be found in 875.101 of the proposed rule.

(4) As is currently the case for same-sex domestic partners, opposite-sex domestic partners will be required to provide documentation to establish that they meet the criteria for domestic partners. This revision can be found in section 875.101 of the proposed rule.

(5) This proposed rule makes other technical conforming amendments to the FLTCIP rules that would be amended by this proposed rule. These changes can be found in section 875.405 of the proposed rule.

Clarification:

(1) We clarify that once coverage has begun, termination of a domestic partnership does not terminate a domestic partner’s insurance coverage as long as the Carrier continues to receive the required premium when due. This revision can be found in section 875.412 of the changes.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because the regulation only adds additional groups to the list of groups eligible to apply for coverage under the FLTCIP. The FLTCIP is a voluntary, self-pay, benefits program with no Government contribution.

Executive Order 12866, Regulatory Review

This rule has been reviewed by the Office of Management and Budget in accordance with Executive Order 12866.

Federalism

We have examined this rule in accordance with Executive Order 13132, Federalism, and have determined that this rule will not have any negative impact on the rights, roles and responsibilities of State, local, or tribal governments.

List of Subjects in 5 CFR Part 875

Administrative practice and procedure, Employee benefit plans, Government contracts, Government employees, health insurance, military personnel, organization and functions, Retirement.

U.S. Office of Personnel Management.

Katherine Archuleta,

Director, U.S. Office of Personnel Management.

Accordingly, OPM is proposing to amend 5 CFR part 875 as follows:

PART 875—FEDERAL LONG TERM CARE INSURANCE PROGRAM

■ 1. The authority citation for part 875 continues to read as follows:

Authority: 5 U.S.C. 9008.

Subpart A—Administration and General Provisions

■ 2. Section 875.101 is amended by revising the definitions of “domestic partner” and “domestic partnership” and by adding in alphabetical order a definition of “stepchild(ren)” to read as follows:

§ 875.101 Definitions.

* * * * *

Domestic partner is defined as a person in a domestic partnership with an employee, annuitant, member of the uniformed services, or retired member of the uniformed services.

Domestic partnership means:

(1) A committed relationship between two adults, of the opposite sex or same sex, in which the partners—

(i) Are each other's sole domestic partner and intend to remain so indefinitely;

(ii) Maintain a common residence, and intend to continue to do so (or would maintain a common residence but for an assignment abroad or other employment-related, financial, or similar obstacle);

(iii) Are at least 18 years of age and mentally competent to consent to a contract;

(iv) Share responsibility for a significant measure of each other's financial obligations;

(v) Are not married or joined in a civil union to anyone else;

(vi) Are not a domestic partner of anyone else;

(vii) Are not related in a way that would prohibit legal marriage in the U.S. jurisdiction in which the domestic partnership was formed;

(viii) Provide documentation demonstrating fulfillment of the requirements of (i) through (vii) as prescribed by OPM; and

(ix) Certify that they understand that willful falsification of the documentation described in subparagraph (viii) of this section may lead to disciplinary action and the recovery of the cost of benefits received related to such falsification and may constitute a criminal violation under 18 U.S.C. 1001.

(2) You or your domestic partner must notify the employing office if at any time between the time of application and the time coverage is scheduled to go into effect, any of the conditions listed in paragraphs (1)(i) through (vii) of this definition are no longer met, in which case a domestic partnership is deemed terminated. Such notification must be made as soon as possible, but in no event later than thirty calendar days after such conditions are no longer met.

* * * * *

Stepchild(ren), as set forth in section 9001 of title 5, United States Code, means the child(ren) of the spouse or domestic partner of an employee, annuitant, member of the uniformed services, or retired member of the uniformed services.

* * * * *

Subpart B—Eligibility

■ 3. Section 875.208 is revised to read as follows:

§ 875.208 May I apply as a qualified relative if the person on whom I am basing my eligibility status has died?

You may not apply as a qualified relative if the workforce member on whom you are basing your qualified relative status died prior to the time you apply for coverage, unless you are receiving a survivor annuity as the spouse or an insurable interest annuity as the domestic partner of a deceased workforce member. In this case, your adult children and your current spouse or domestic partner are also considered to be qualified relatives.

■ 4. In § 875.213, paragraph (a) is revised to read as follows:

§ 875.213 May I apply as a qualified relative if I am the domestic partner of a workforce member?

(a) You may apply for coverage as a qualified relative if you are a domestic partner, as described in section 875.101 of this chapter. As prescribed by OPM, you will be required to provide documentation to demonstrate that you meet these requirements, and you must submit to full underwriting requirements. However, as explained in section 875.210 of this chapter, if you lose your status as a domestic partner, and therefore a qualified relative, before your coverage goes into effect, you are no longer eligible for FLTCIP coverage.

* * * * *

Subpart D—Coverage

■ 5. Section 875.405 is revised to read as follows:

§ 875.405 If I marry, may my new spouse apply for coverage? If I become a domestic partner, may my new domestic partner apply for coverage? May other qualified relatives apply for coverage?

(a)(1) If you are an active workforce member and you have married, your spouse is eligible to submit an application for coverage under this section within 60 days from the date of your marriage and will be subject to the underwriting requirements in force for the spouses of active workforce members during the most recent open season. You, however, are not eligible for abbreviated underwriting because of your marriage. You, your spouse, or both you and your spouse may apply for coverage during this 60-day period, but full underwriting will be required for you. After 60 days from the date of your marriage, you and/or your spouse may still apply for coverage but will be subject to full underwriting.

(2) If you are an active workforce member and you have entered into a domestic partnership, your domestic partner is eligible to submit an application for coverage under this section at any time from the commencing date of your domestic partnership and will be subject to full underwriting requirements. You are not eligible for abbreviated underwriting because of your domestic partnership. You, your domestic partner, or both you and your domestic partner may apply for coverage at any time, but full underwriting will be required for both of you.

(b) The new spouse or domestic partner of an annuitant or retired member of the uniformed services may apply for coverage with full underwriting at any time following the

marriage or commencing date of the domestic partnership.

(c) Other qualified relative(s) of a workforce member may apply for coverage with full underwriting at any time following the marriage or commencing date of the domestic partnership.

■ 6. In § 875.412, the introductory text is revised and paragraph (e) is added to read as follows:

§ 875.412 When will my coverage terminate?

Except as provided in paragraph (e) of this section, your coverage will terminate on the earliest of the following dates:

* * * * *

(e) Termination of a domestic partnership does not terminate insurance coverage as long as the Carrier continues to receive the required premium when due.

[FR Doc. 2014-26779 Filed 11-12-14; 8:45 am]

BILLING CODE 6325-63-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2014-0756; Directorate Identifier 2014-NM-103-AD]

RIN 2120-AA64

Airworthiness Directives; the Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all the Boeing Company Model 707 airplanes, and Model 720 and 720B series airplanes. This proposed AD is intended to complete certain mandated programs intended to support the airplane reaching its limit of validity (LOV) of the engineering data that support the established structural maintenance program. This proposed AD would require repetitive inspections for cracking of the inboard and outboard midspar fittings of the nacelle struts and of the torque bulkhead, midspar chords, drag fitting, and front spar support, and doing applicable related investigative and corrective actions; replacing the midspar fittings; and doing other specified actions. We are proposing this AD to detect and correct cracking in the midspar fittings of the inboard and outboard nacelle struts, which could

result in the loss of the structural integrity of the midspar fitting. This condition could cause an unsafe separation of the engine and consequent wing fire.

DATES: We must receive comments on this proposed AD by December 29, 2014.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Fax: 202-493-2251.
- Mail: U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- Hand Delivery: Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone 206-544-5000, extension 1; fax 206-766-5680; Internet <https://www.myboeingfleet.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2014-0756; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800-647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Chandra Ramdoss, Aerospace Engineer, Airframe Branch, ANM-120L, FAA, Los Angeles Aircraft Certification Office (ACO), 3960 Paramount Boulevard, Lakewood, CA 90712-4137; phone: 562-627-5239; fax: 562-627-5210; email: chandraduth.ramdoss@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2014-0756; Directorate Identifier 2014-NM-103-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

As described in FAA Advisory Circular 120-104 (http://www.faa.gov/documentLibrary/media/Advisory_Circular/120-104.pdf), several programs have been developed to support initiatives that will ensure the continued airworthiness of aging airplane structure. The last element of those initiatives is the requirement to establish a limit of validity (LOV) of the engineering data that support the structural maintenance program under 14 CFR 26.21. This proposed AD is the result of an assessment of the previously established programs by Boeing during the process of establishing the LOV for Model 707 airplanes and Model 720 and 720B series airplanes. The actions specified in this proposed AD are necessary to complete certain programs to ensure the continued airworthiness of aging airplane structure and to support an airplane reaching its LOV.

We received reports of cracked midspar fittings on the inboard and outboard nacelle struts. The airplanes had accumulated between 9,900 and 63,000 total flight hours. Five of these airplanes had cracked midspar fittings that resulted in separation of the inboard strut and engine from the airplane inflight. In two of those events the inboard nacelle strut contacted the outboard engine, causing it to separate from the airplane. Operators have also reported cracking in the transition radius of the inboard and outboard midspar fittings of the nacelle struts of the numbers 1 and 4 engines.

The reported cracks on the inboard and outboard midspar fittings of the nacelle struts of engines numbers 1, 2, 3, and 4 were found to be vertical at the

lug hole or across the double horizontal tangs at the radius where the tangs merge with the lug. Analysis determined that the 4330 steel midspar fittings cracked as a result of stress corrosion and fatigue at the lug and fatigue at the tangs.

Cracked midspar fittings, if not detected and corrected, could result in the loss of the structural integrity of the midspar fitting. This condition could cause an unsafe separation of the engine and consequent wing fire.

Relevant Service Information

We reviewed Boeing 707 Alert Service Bulletin A3183, Revision 6, dated February 7, 2014. For information on the procedures and compliance times, see this service information at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2014–0756.

Related Rulemaking

AD 93–11–02, Amendment 39–8594, Docket No. 92–NM–230–AD, which applies to The Boeing Company Model 707 and 720 series airplanes, requires repetitive inspections for cracking of the midspar fittings on the inboard struts, related investigative and corrective actions if necessary, and replacement of the midspar fittings with new, improved fittings, which constitutes terminating action for the repetitive inspections.

AD 2012–16–12, Amendment 39–17159 (77 FR 49708, August 17, 2012), which applies to The Boeing Company Model 707 airplanes, and Model 720 and 720B series airplanes, requires a detailed inspection of the midspar fittings of the nacelle struts for engine numbers 2 and 3 to confirm that the correct part number is installed, and installing the correct part number if it is not installed. The correct part number is the new, improved midspar fitting required by AD 93–11–02, Amendment 39–8594, Docket No. 92–NM–230–AD.

AD 2012–16–12 also requires repetitive high frequency eddy current inspections (HFEC) of the midspar fittings of engine numbers 2 and 3 nacelle struts for cracks and repair if necessary. In addition, AD 2012–16–12 requires repetitive general visual inspections of the nacelle struts of engine numbers 1, 2, 3, and 4 to verify that the nacelle strut has not drooped below its normal position, and repair if necessary.

FAA’s Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the inspections for cracking of the inboard and outboard midspar fittings of the nacelle struts and of the torque bulkhead, midspar chords, drag fitting, and front spar support, and doing applicable related investigative and corrective actions; replacing the midspar fittings; and doing other specified actions; as specified in parts 2 through 6, inclusive, of the Accomplishment Instructions of the service information described previously, except as discussed under “Differences Between this Proposed AD and the Service Information.”

The phrase “related investigative actions” is used in this proposed AD. “Related investigative actions” are follow-on actions that (1) are related to the primary actions, and (2) further investigate the nature of any condition found. Related investigative actions in an AD could include, for example, inspections.

The phrase “corrective actions” is used in this proposed AD. “Corrective actions” are actions that correct or address any condition found. Corrective

actions in an AD could include, for example, repairs.

The phrase “other specified actions” is used in this proposed AD. Other specified actions in this proposed AD include installing new inboard and outboard midspar fittings, installing oversized fasteners in the two forward most fastener holes common to the inboard side of the nacelle strut overwing support fitting and the wing front spar upper chord, applying sealant to the midspar area, and applying corrosion inhibiting compound to the midspar fitting areas.

We have determined that the actions specified in table 1 of paragraph 1.E., “Compliance,” of Boeing 707 Alert Service Bulletin A3183, Revision 6, dated February 7, 2014, should not be required in this AD, as noted in the service bulletin.

Differences Between This Proposed AD and the Service Information

Boeing 707 Alert Service Bulletin A3183, Revision 6, dated February 7, 2014, specifies to contact the manufacturer for fitting installation instructions and instructions on how to repair certain conditions, but this proposed AD would require doing those corrective actions in one of the following ways:

- In accordance with a method that we approve; or
- Using data that meet the certification basis of the airplane, and that have been approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) whom we have authorized to make those findings.

Costs of Compliance

We estimate that this proposed AD affects 12 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS				
Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspections	214 work-hours × \$85 per hour = \$18,190 per inspection cycle.	\$0	\$18,190	\$218,280.
Replacement of midspar fitting.	18 work-hours × \$85 per hour = \$1,530	Up to \$7,867	Up to \$9,397	Up to \$112,764.
Mid-interval inspections ..	107 work-hours × \$85 per hour = \$9,095 per inspection cycle.	\$0	\$9,095	\$109,140.

We estimate the following costs to do any additional inspections that would

be required based on the results of the proposed inspections. We have no way

of determining the number of aircraft that might need these inspections:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Inspections	Up to 21 work-hours × \$85 per hour = \$1,785	\$0	\$1,785

We have received no definitive data that would enable us to provide cost estimates for the on-condition corrective actions specified in this AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

The Boeing Company: Docket No. FAA–2014–0756; Directorate Identifier 2014–NM–103–AD.

(a) Comments Due Date

We must receive comments by December 29, 2014.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company Model 707–100 long body, –200, –100B long body, and –100B short body series airplanes; Model 707–300, –300B, –300C, and –400 series airplanes; and Model 720 and 720B series airplanes; certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 54, Nacelles/Pylons.

(e) Unsafe Condition

This AD was prompted by certain mandated programs intended to support the airplane reaching its limit of validity (LOV) of the engineering data that support the established structural maintenance program. We are issuing this AD to detect and correct cracking in the midspar fittings of the inboard and outboard nacelle struts, which could result in the loss of the structural integrity of the midspar fitting. This condition could cause an unsafe separation of the engine and consequent engine fire.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Inspections of Nacelle Struts and Surrounding Structure and Replacement of Inboard and Outboard Midspair Fittings

At the applicable time specified in table 2 or table 3 of paragraph 1.E., "Compliance," of Boeing 707 Alert Service Bulletin A3183,

Revision 6, dated February 7, 2014, except as required by paragraph (i)(1) of this AD: Do the inspections required by paragraphs (g)(1), (g)(2), and (g)(3) of this AD in accordance with part 2 or part 3, as applicable, of the Accomplishment Instructions of Boeing Alert Service Bulletin A3183, Revision 6, dated February 7, 2014, except as required by paragraph (i)(2) of this AD. Before further flight, do all applicable related investigative and corrective actions, replace the inboard and outboard midspair fittings with new parts, and do other specified actions (including installing new bushings and oversize fasteners) in accordance with part 2 or part 3, as applicable, of the Accomplishment Instructions of Boeing Alert Service Bulletin A3183, Revision 6, dated February 7, 2014, except as required by paragraph (i)(2) of this AD. Repeat the inspections required by paragraphs (g)(1), (g)(2), and (g)(3) of this AD thereafter at the applicable intervals specified in table 2 or table 3 of paragraph 1.E., "Compliance," of Boeing 707 Alert Service Bulletin A3183, Revision 6, dated February 7, 2014, except as required by paragraph (i)(1) of this AD.

(1) A detailed inspection and a high frequency eddy current inspection (HFEC) for cracks in the inboard and outboard midspair fittings of the nacelle struts.

(2) Open hole HFEC inspections for cracks in the torque bulkhead, midspair chords, drag fitting, and front spar support.

(3) A surface HFEC inspection of the front spar support for cracks.

(h) Mid-Interval Inspections and Replacement of Nacelle Strut Midspair Fittings

At the applicable time specified in table 4 or 5 of paragraph 1.E., "Compliance," of Boeing 707 Alert Service Bulletin A3183, Revision 6, dated February 7, 2014: Do the inspections required by paragraphs (h)(1), (h)(2), and (h)(3) of this AD, in accordance with part 4 or part 5, as applicable, of the Accomplishment Instructions of Boeing Alert Service Bulletin A3183, Revision 6, dated February 7, 2014, except as required by paragraph (i)(2) of this AD. Do all applicable related investigative, corrective, and other specified actions (including installing new bushings and oversize fasteners) before further flight. Repeat the inspections required by paragraphs (h)(1), (h)(2), and (h)(3) of this AD thereafter at the applicable intervals specified in table 4 or 5 of paragraph 1.E., "Compliance," of Boeing 707 Alert Service Bulletin A3183, Revision 6, dated February 7, 2014. The threshold for the repetitive inspections required by paragraphs (h)(1), (h)(2), and (h)(3) of this AD is 1,500 flight cycles or 48 months, whichever occurs first, since the most recent midspair fitting replacement.

(1) A detailed inspection and a surface HFEC inspection for cracks in the inboard

and outboard midspar fittings of the nacelle struts.

(2) An open hole HFEC inspection for cracks in the drag fitting and front spar support.

(3) A surface HFEC inspection for cracks in the front spar support.

(i) Exceptions to Service Information Specifications

(1) Where Boeing 707 Alert Service Bulletin A3183, Revision 6, dated February 7, 2014, specifies a compliance time "after the Revision 6 date of this service bulletin," this AD requires compliance within the specified compliance time after the effective date of this AD.

(2) Where Boeing 707 Alert Service Bulletin A3183, Revision 6, dated February 7, 2014, specifies to contact Boeing for appropriate action: Do corrective actions before further flight using a method approved in accordance with the procedures specified in paragraph (k) of this AD.

(j) Special Flight Permit

Special flight permits, as described in Section 21.197 and Section 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199), are not allowed.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (l)(1) of this AD. Information may be emailed to: 9-ANM-LAACO-AMOC-Requests@faa.gov.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Los Angeles ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane and the approval must specifically refer to this AD.

(l) Related Information

(1) For more information about this AD, contact Chandra Ramdoss, Aerospace Engineer, Airframe Branch, ANM-120L, FAA, Los Angeles Aircraft Certification Office (ACO), 3960 Paramount Boulevard, Lakewood, CA 90712-4137; phone: 562-627-5239; fax: 562-627-5210; email: chandrathuth.ramdoss@faa.gov.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone 206-544-5000, extension 1; fax 206-766-5680;

Internet <https://www.myboeingfleet.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

Issued in Renton, Washington, on November 5, 2014.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014-26837 Filed 11-12-14; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2014-0903; Directorate Identifier 2013-SW-043-AD]

RIN 2120-AA64

Airworthiness Directives; Airbus Helicopters Deutschland GmbH (Previously Eurocopter Deutschland GmbH) (Airbus Helicopters)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for Airbus Helicopters Model EC135P1, EC135P2, EC135P2+, EC135T1, EC135T2, and EC135T2+ helicopters. This proposed AD would require reducing the life limit of certain parts and removing each part that has reached its life limit. The proposed actions are intended to reduce the life limits of certain critical parts to prevent failure of a part and subsequent loss of control of the helicopter.

DATES: We must receive comments on this proposed AD by January 12, 2015.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Docket:* Go to <http://www.regulations.gov>. Follow the online instructions for sending your comments electronically.
- *Fax:* 202-493-2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001.
- *Hand Delivery:* Deliver to the "Mail" address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the European Aviation Safety Agency (EASA) AD, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (telephone 800-647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Matt Fuller, Senior Aviation Safety Engineer, Safety Management Group, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222-5110; email matthew.fuller@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

Discussion

EASA, which is the Technical Agent for the Member States of the European Union, issued EASA AD No. 2013-0178, dated August 7, 2013, to correct an unsafe condition for the Eurocopter Deutschland GmbH (ECD) (now Airbus Helicopters) Model EC135P1, EC135P2, EC135P2+, EC135T1, EC135T2, EC135T2+, EC635T1, EC635P2+, and EC635T2+ helicopters. EASA advises that ECD has revised the airworthiness limitations for the EC135 and EC635

type design as published in the Master Servicing Manual (MSM) EC135 Chapter 04—Airworthiness Limitations Section (ALS) documents. Revision 14 of the MSM contains these new airworthiness limitations. EASA states that failure to comply with these limitations could result in an unsafe condition. For these reasons, EASA AD No. 2013–0178 requires revising the ALS to include the new life limits and replacing each part that has reached its life limit.

FAA's Determination

These helicopters have been approved by the aviation authority of Germany and are approved for operation in the United States. Pursuant to our bilateral agreement with Germany, the EASA, its technical representative, has notified us of the unsafe condition described in its AD. We are proposing this AD because we evaluated all known relevant information and determined that an unsafe condition is likely to exist or develop on other products of the same type design.

Related Service Information

The airworthiness limitations and maintenance procedures for certain parts are contained in the Airworthiness Limitations section, Chapter 4, of Eurocopter's MSM EC135, dated December 1, 2001. Revision 14 of the MSM, dated July 1, 2012, establishes a life limit for certain part-numbered main rotor blades and reduces the life limits for swashplate and mixing lever gear unit parts.

Proposed AD Requirements

This proposed AD would require, before further flight, revising the ALS of the applicable maintenance manual and the component history card or equivalent record by reducing the life limit for various parts and removing from service any part that has reached its life limit.

Differences Between This Proposed AD and the EASA AD

This proposed AD does not apply to Airbus Helicopters Model EC635T1, P2+, or EC635T2+ helicopters because those helicopters are not type certificated in the U.S.

Costs of Compliance

We estimate that this proposed AD would affect 267 helicopters of U.S. Registry.

We estimate that operators may incur the following costs in order to comply with this AD. Labor costs are estimated at \$85 per hour. We estimate 2 work hours to update the maintenance

manual for a total cost of \$170 for each helicopter and \$45,390 for the U.S. fleet.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed, I certify this proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Airbus Helicopters Deutschland GmbH (Previously Eurocopter Deutschland GmbH): Docket No. FAA–2014–0903; Directorate Identifier 2013–SW–043–AD.

(a) Applicability

This AD applies to Model EC135P1, EC135P2, EC135P2+, EC135T1, EC135T2, and EC135T2+ helicopters, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as failure of a critical part, which could result in loss of control of the helicopter.

(c) Comments Due Date

We must receive comments by January 12, 2015.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

Before further flight:

- (1) Revise the life limit of each part listed in paragraphs (e)(1)(i) through (ii) in the Airworthiness Limitations Section of the applicable maintenance manual and record the revised life limit on the component history card or equivalent record as follows:

(i) For swashplate parts:

(A) Ring (bearing ring), part number (P/N) L623M2001214, reduce the life limit from 8,300 hours time-in-service (TIS) to 8,000 hours TIS.

(B) Ring (control ring), P/N L623M2001213, reduce the life limit from 8,300 hours TIS to 8,000 hours TIS.

(C) Cardan ring (two-part), P/N L623M2005205, reduce the life limit from 14,400 hours TIS to 12,900 hours TIS.

(D) Bolt (control ring), P/N L671M7001215, reduce the life limit from 14,400 hours TIS to 12,900 hours TIS.

(E) Bolt (sliding sleeve), P/N L623M2006206 and P/N L623M2006213, reduce the life limit from 14,400 hours TIS to 12,900 hours TIS.

(ii) For mixing lever gear unit parts:

(A) Forked lever assembly, P/N L671M3012102, reduce the life limit from 9,000 hours TIS to 8,700 hours TIS.

(B) Hinged support, P/N L671M7003210, reduce the life limit from 8,700 hours TIS to 8,400 hours TIS.

(C) Bolt, P/N L671M7001220, reduce the life limit from 8,700 hours TIS to 8,400 hours TIS.

- (2) Remove from service any part listed in paragraph (e)(1) of this AD that has reached or exceeded its newly revised life limit.

(f) Special Flight Permit

Special flight permits are limited to a one-time flight to a maintenance facility to replace a part that has reached its life limit.

(g) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Matt Fuller, Senior Aviation Safety Engineer, Safety Management Group, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222-5110; email matthew.fuller@faa.gov.

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(h) Additional Information

The subject of this AD is addressed in European Aviation Safety Agency (EASA) AD 2013-0178, dated August 7, 2013. You may view the EASA AD on the Internet at <http://www.regulations.gov> in Docket No. FAA-2014-0903.

(i) Subject

Joint Aircraft Service Component (JASC) Code: 6300, 2700 Swashplate Ring, Cardan Ring, Bolt, Mixing Lever Gear Unit (flight controls).

Issued in Fort Worth, Texas, on October 28, 2014.

Kim Smith,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2014-26836 Filed 11-12-14; 8:45 am]

BILLING CODE 4910-13-P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

14 CFR Part 1251

[Document Number NASA-2014-0011]

RIN 2700-AD85

Discrimination on the Basis of Disability in Federally Assisted Programs and Activities

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The National Aeronautics and Space Administration (NASA) is proposing to amend its rules implementing Section 504 of the Rehabilitation Act of 1973 (section 504), which prohibits discrimination on the basis of disability in programs, services, and activities by recipients of Federal financial assistance from NASA as well as those programs, services, and activities conducted by NASA. The

revisions to this rule are part of NASA's retrospective plan under EO 13563 completed in August 2011.

DATES: Submit comments on or before December 15, 2014.

ADDRESSES: Comments must be identified with RIN 2700-AD85 and may be sent to NASA via the *Federal E-Rulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Please note that NASA will post all comments on the internet with changes, including any personal information provided.

NASA's full plan can be accessed at: <http://www.nasa.gov/open/>.

FOR FURTHER INFORMATION CONTACT: Robert Cosgrove, (202) 358-0446.

SUPPLEMENTARY INFORMATION:**Background**

In this rulemaking, NASA is proposing to amend its section 504 regulations to incorporate changes to the definition of disability required by the Americans with Disabilities Act (ADA) Amendments Act of 2008, include an affirmative statement of the longstanding requirement for reasonable accommodations in programs, services, and activities, include a definition of direct threat and a provision describing the parameters of the existing direct threat defense to a claim of discrimination, clarify the existing obligation to provide auxiliary aids and services to qualified individuals with disabilities, update the methods of communication that recipients may use to inform program beneficiaries of their obligation to comply with section 504 to reflect changes in technology, adopt updated accessibility standards applicable to the design, construction, and alteration of buildings and facilities, establish time periods for compliance with these updated accessibility standards, provide NASA with access to recipient data and records to determine compliance with section 504, and make administrative updates to correct titles.

NASA is also proposing to amend its regulation to incorporate changes required by the Rehabilitation Act Amendments of 1992 (1992 Amendments) by revising current sections 1251.2—Employment Practices (Federally Assisted Programs) and 1251.540—Employment (Federally Conducted Programs) and instead referencing the EEOC's ADA title I regulation. The proposed rule also updates outdated terminology and references that currently exist in Part 1251 and changes the word "handicapped" and similar variations of that word that appear throughout Part 1251, replacing it with "people first"

language (e.g., "individuals with disabilities") consistent with the 1992 Amendments.

Section 504

NASA implements the requirements of Section 504 of the Rehabilitation Act of 1973 (section 504), which prohibits discrimination on the basis of disability in Federally conducted and assisted programs or activities, through its regulation in Part 1251. NASA's section 504 regulation applies to recipients to whom the Agency extends Federal financial assistance, such as research, education and training grants, and cooperative agreements, as well as programs, services, and activities conducted by NASA. NASA's section 504 regulation at § 1251.103 prohibits denial of the benefits of, exclusion from participation in, or other discrimination against qualified individuals with disabilities in programs or activities because a recipient's facilities are inaccessible to or unusable by persons with disabilities. Many of the entities that receive financial assistance from NASA are also covered by Title II of the ADA (title II), which prohibits discrimination on the basis of disability by public entities (i.e., state and local governments and their agencies) or Title III of the ADA (title III), which prohibits discrimination on the basis of disability by: (1) Public accommodations (i.e., private entities that own, operate, lease, or lease to places of public accommodation); (2) newly constructed and altered commercial facilities; and (3) private entities that offer certain examinations and courses related to educational and occupational certification.

Definition of Disability—ADA Amendments Act of 2008

The ADA Amendments Act of 2008 (the ADA Amendments Act) was signed into law in September 2008 and became effective on January 1, 2009. Congress enacted the ADA Amendments Act to revise the ADA definition of disability in order to ensure that this definition is broadly construed and applied without extensive analysis and to supersede Supreme Court decisions that had too narrowly interpreted the ADA's definition of a disability. The ADA Amendments Act not only amended the definition of disability applicable to the ADA but also amended the Rehabilitation Act of 1973 to conform the section 504 definition of disability at 29 U.S.C. 705(20)(B) to the revised ADA definition. In this rulemaking, NASA is proposing to amend its section 504

regulation to implement these revised requirements. NASA intends these proposed regulatory changes to be consistent with the Department of Justice's (DOJ's) proposed changes to its title II regulation to incorporate the requirements of the ADA Amendments Act published on January 30, 2014 [79 FR 4839].

Due to the changes that the ADA Amendments Act made to the application of the definition of disability, participants in recipients' programs, services, and activities who, in the past decade, may not have been determined to have a disability under section 504 and title II may now in fact be found to have a disability under those laws. Section 504 and the ADA define disability as (1) a physical or mental impairment that substantially limits a major life activity; (2) a record of such impairment; or (3) being regarded as having such an impairment [29 U.S.C. 705(9)(B); 42 U.S.C. 12102(1)]. The ADA Amendments Act does not alter these three elements of the definition of disability in the ADA and section 504, but it significantly changes how the term "disability" is to be interpreted and adds important rules of construction to inform that interpretation. Specifically, Congress directed that the definition of disability shall be construed broadly and that the determination of whether an individual has a disability should not demand extensive analysis [42 U.S.C. 12102].

NASA's proposed revisions to the definition of disability are all based on specific provisions in the ADA Amendments Act or specific language in the legislative history. Since the ADA Amendments Act does not change the meaning of the term "physical or mental impairment," NASA is retaining the general regulatory definitions for this term with only minor modifications consistent with DOJ's proposed revisions to its Title II ADA regulations. First, NASA is proposing to add examples of two new body systems—the immune system and the circulatory system—that may be affected by a physical impairment. See 14 CFR 1251.102(h)(2)(A). In addition, "dyslexia" will be added to 14 CFR 1251.102(h)(2)(A) as one example of a specific learning disability that falls within the meaning of the phrase "physical or mental impairment."

The proposed revisions also expand the definition of "major life activities" by providing a non-exhaustive list of major life activities and specifically including the operation of major bodily functions. Prior to the ADA Amendments Act, section 504 did not define "major life activities," leaving

delineation of illustrative examples to agency regulations. The definition of "disability" in the NASA's current section 504 regulations states that "[m]ajor life activities means functions such as caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, and working." See 14 CFR 1251.102(h)(2)(ii). The ADA, as amended, incorporates into the statutory language a non-exhaustive list of major life activities that includes, but is not limited to, "caring for oneself, performing manual tasks, seeing, hearing, eating, sleeping, walking, standing, lifting, bending, speaking, breathing, learning, reading, concentrating, thinking, communicating, and working." See 42 U.S.C. 12102(2)(A). This list reflects Congress's concern that courts were interpreting the term "major life activities" more narrowly than Congress intended. See 42 U.S.C. 12101(b)(4). In §§ 1251.102(h) and 1251.503(h), NASA proposes to revise its section 504 regulatory definitions of disability to incorporate the statutory examples as well as to provide additional examples included in the EEOC title I final regulation—reaching, sitting, and interacting with others. See 29 CFR 1630.2(i)(1)(i).

These proposed revisions also add rules of construction that should be applied when determining whether an impairment substantially limits a major life activity. The rules of construction state the following:

- That the term "substantially limits" shall be construed broadly in favor of expansive coverage, to the maximum extent permitted by the terms of the ADA;
- that an impairment is a disability if it substantially limits the ability of an individual to perform a major life activity as compared to most people in the general population;
- that the primary issue in a case brought under the ADA should be whether the covered entity has complied with its obligations and whether discrimination has occurred, not the extent to which the individual's impairment substantially limits a major life activity;
- that in making the individualized assessment required by the ADA, the term "substantially limits" shall be interpreted and applied to require a degree of functional limitation that is lower than the standard for "substantially limits" applied prior to the ADA Amendments Act;
- that the comparison of an individual's performance of a major life activity to the performance of the same major life

activity by most people in the general population usually will not require scientific, medical, or statistical evidence;

- that mitigating measures other than "ordinary eyeglasses or contact lenses" shall not be considered in assessing whether an individual has a "disability" (mitigating measures include medications, prosthetic devices, assistive devices, or learned behavioral or adaptive neurological modifications that an individual may use to eliminate or reduce the effects of an impairment);
- that an impairment that is episodic or in remission is a disability if it would substantially limit a major life activity when active; and
- that an impairment that substantially limits one major life activity need not substantially limit other major life activities in order to be considered a substantially limiting impairment.

In keeping with the ADA Amendments Act, the proposed rule provides that if a person seeks to establish coverage under section 504 using the "regarded as" prong of the disability definition, that individual need only establish that he or she has been subjected to an act prohibited by section 504 because of an actual or perceived physical or mental impairment. An individual will not be "regarded as" a person with a disability if the impairment is both transitory (meaning that it has an actual or expected duration of six months or less) and minor. ADA Amendments Act, section 4(a) (codified as amended at 42 U.S.C. 12102).

Definition of Auxiliary Aids and Services

Although NASA's existing section 504 Federally assisted regulation referenced the provision of auxiliary aids,¹ it did not include a definition. The proposed regulation includes a definition for auxiliary aids and services, which is consistent with the definition used in the ADA title II regulation at 28 CFR 35.104.

Employment

NASA proposes to revise Section 1251.2—Employment Practices (Federally Assisted Programs) and Section 1251.540—Employment (Federally Conducted Programs) to conform to the Rehabilitation Act Amendments of 1992 (Pub. L. 102–569, sec. 506) which amended title V to make

¹ Although the current regulation references "auxiliary aids," the term has always been understood to mean "auxiliary aids and services," and the revised regulation references them correctly.

the same employment standards set forth in title I of the ADA apply to employment discrimination apply under section 504. As such, the proposed rule deletes the existing requirements related to discriminatory employment practices and references the standards applied under Title I of the Americans with Disabilities Act of 1990 (42 U.S.C. 12111 *et seq.*) and to the extent such sections relate to employment, the provisions of sections 501 through 504 and 510 of the Americans with Disabilities Act of 1990 (42 U.S.C. 12201–12204 and 12210), and the Equal Employment Opportunity Commission's ADA title I regulation at 29 CFR § 1630, as amended.

NASA is also proposing to clarify its role in the processing and coordination of complaints alleging discrimination by its recipients, Title I of the ADA (title I) prohibits discrimination against individuals with disabilities employed in a business that has fifteen or more employees. Title I is enforced by the United States Equal Employment Opportunity Commission (EEOC) and is the designated Federal agency for the processing and adjudication of all complaints filed under title I. Many of the Agency's recipients may fall under the jurisdiction of title I and may also file a complaint alleging discrimination under section 504. NASA has authority to receive complaints of discrimination and has developed procedures to identify when NASA has jurisdiction to process such complaints or when they must be referred to the EEOC or DOJ for processing. In order to avoid duplication of investigative and enforcement efforts, NASA will process and coordinate any complaints filed under this Part in accordance with the Equal Employment Opportunity Commission (EEOC) procedures set forth in 29 CFR part 1640 and the Department of Justice (DOJ) procedures set forth at 28 CFR part 37 (Procedures for Coordinating the Investigation of Complaints or Charges of Employment Discrimination Based on Disability Subject to the Americans with Disabilities Act and Section 504 of the Rehabilitation Act of 1973).

NASA is also proposing to clarify its role in the processing and adjudication of section 504 complaints in its Federally conducted programs.

Provision of Auxiliary Aids and Services

NASA's current section 504 Federally assisted regulation at § 1251.103(b)(3) provides that "[r]ecipients shall take appropriate steps to ensure that no handicapped individual is denied the benefits of, excluded from participation

in, or otherwise subjected to discrimination in any program or activity receiving Federal financial assistance because of the absence of auxiliary aids for individuals with impaired sensory, manual, or speaking skills."

This Notice of Proposed Rule Making (NPRM) proposes to clarify this existing obligation by providing affirmative language explaining this obligation. Similar language is already included in NASA's Federally conducted regulation at § 1251.560. (Communications)

Notice of Recipient Obligations To Comply With Section 504

NASA's section 504 regulations at § 1251.107(a) require a recipient that employs 15 or more persons to take appropriate initial and continuing steps to notify participants, beneficiaries, applicants, and employees, including those with or hearing and vision disabilities, and unions or professional organizations holding collective bargaining or professional agreements with the recipient that it does not discriminate on the basis of disability in violation of section 504 and this part. The notification shall state, where appropriate, that the recipient does not discriminate in admission or access to, or treatment or employment in, its programs or activities. The notification shall also include an identification of the responsible employee designated to coordinate the recipient's efforts to comply with section 504 pursuant to § 1251.106(a). The regulation requires the recipient to make the initial notification required by this paragraph within 90 days of the effective date of this part. This regulation also delineates the methods of initial and continuing notification to include "the posting of notices, publication in newspapers and magazines, placement of notices in recipient's publication, and distribution of memoranda or other written communications." NASA recognizes that the methods by which a recipient communicates with interested persons has changed significantly since these regulations were promulgated and this regulation as currently written does not reflect the current and future state of information dissemination. With the advent of broad application of the Internet and the Web, as well as electronic publishing, electronic mail, text messaging, and social media platforms, NASA has determined that the regulation does not adequately include electronic methods of communication. Furthermore, NASA's grant recipients currently rely on their Web sites, email, text messaging, and social media to communicate with and

provide information to the beneficiaries of its programs, services, and activities. Many of the publications that were available in print such as pamphlets, brochures, maps, course catalogs, policies, and procedures are now posted on the recipients' Web sites and can be printed or downloaded by the interested person viewing the Web site. In revising the regulation to include electronic communications, NASA is also providing its grant recipients the ability to provide this information in a more cost-effective and expeditious manner than by relying on printed media. Information or programs provided to the public on recipient's Web sites should be provided in an accessible format in order to ensure equal access to the recipient's programs, services, and activities.

Accessibility Standards for New Construction

NASA's section 504 regulations at § 1251.302(c) require that if construction of a recipient's facility commenced after the effective date of the regulations (January 18, 1991), the facility must be designed and constructed so that it is readily accessible to and usable by persons with disabilities. These regulations also require that facility alterations commenced after January 18, 1991, that affect or may affect the facility's usability must be accomplished so that, to the maximum extent feasible, the altered portion of the facility is readily accessible and usable by persons with disabilities.

For facilities subject to the new construction and alterations requirements, the NASA regulation at § 1251.302(c) has always incorporated by reference an accessibility design standard, such that construction or alterations in conformance with that standard would be deemed in compliance with NASA's section 504 regulation. Under the current regulation, new construction or alterations made in conformance with the Uniform Federal Accessibility Standards (UFAS) are deemed to be in compliance with NASA's section 504 regulation, although a recipient may depart from UFAS when other methods provide equivalent or greater access to and usability of the facility.

The adoption of UFAS as an accessibility design standard in NASA's section 504 regulation occurred in 1991 as part of a joint rulemaking with other Federal agencies, led by the DOJ pursuant to its coordinating authority for section 504 under Executive Order 12250. [51 FR 26862 July 28, 1986, as amended and 55 FR 52138, 52140, December 19, 1990]. NASA and the

other participating agencies adopted UFAS (effective January 18, 1991) to diminish the possibility that some recipients of Federal financial assistance would face conflicting enforcement standards either between section 504 and the Architectural Barriers Act of 1968, or among the section 504 regulations of different Federal agencies. [55 FR 52136–37 (1990)]

Accessibility Standards in the ADA Regulations Issued by DOJ

DOJ's 1991 title II ADA regulation incorporated by reference two sets of standards for new construction and alterations: UFAS and the 1991 ADA Standards for Accessible Design (1991 Standards) except that the elevator exemption contained at sections 4.1.3(5) and 4.1.6(1)(k) of the 1991 Standards did not apply. The 1991 title II ADA regulations also permitted departures from the particular requirements of either standard by the use of other methods when it was clearly evident that equivalent access to the facility or part of the facility is thereby provided. UFAS was included as an option for title II entities because it was deemed the accessibility standard under existing section 504 accessibility regulations. UFAS was not an accessibility option under the ADA for title III entities, even if they were also subject to an agency section 504 regulation.

On September 15, 2010, DOJ published revised title II and title III ADA regulations that included the adoption of revised accessibility standards, the 2010 ADA Standards for Accessible Design (2010 Standards). [75 FR 56164]. The 2010 Standards were based on the 2004 ADA Accessibility Guidelines adopted by the United States Access Board in 2004. (36 CFR parts 1190 and 1191). The 2010 Standards, which now supersede the 1991 Standards, were adopted by DOJ through formal rulemaking and were subject to substantial scrutiny and deliberation, including consideration of costs and benefits. Compliance with the 2010 Standards was required for all new construction and alterations that commenced on or after March 15, 2012. [75 FR 56164, 56182 (Sept. 15, 2010)]. As of March 15, 2012, UFAS was no longer an option for compliance with title II.

NASA's Revisions to Its Section 504 Federally Assisted Regulations To Adopt the 2010 Standards

In the preamble to the final title II regulation, DOJ stated that Federal agencies that extend Federal financial assistance should revise their section 504 regulations to adopt the 2010

Standards as section 504 standards for new construction and alterations [75 FR 56164, 56213 Sep. 15, 2010]. DOJ also stated its intent to work with Federal agencies "to revise their section 504 regulations in the near future to adopt the 2010 Standards as the appropriate accessibility standard for their recipients." In coordination with DOJ, we are adopting the 2010 Standards as set forth in 28 CFR part 35, in lieu of UFAS, for new construction and alterations commencing on or after one year from the publication date of the final rule in the **Federal Register**. Therefore, as discussed below, the proposed rule specifies that all buildings and facilities newly constructed or altered by recipients shall comply with the requirements for a "public building or facility" as set forth in the 2010 Standards.

Under NASA's section 504 regulations, the same accessibility standards for new construction and alterations are applied to all recipients regardless of whether they are public or private entities that have an obligation to comply with title II or title III of the ADA, respectively. That is, both private and public recipients are subject to the same requirements for the purposes of compliance with NASA's section 504 regulations. The 2010 Standards impose several different requirements for buildings and facilities covered by title II as compared to buildings and facilities covered by title III. For example, Exception 1 of section 206.2.3 of the 2010 Standards exempts certain multistory buildings owned by private entities from the requirement to provide an elevator. This exemption does not apply to buildings owned by public entities. Similarly, the 2010 Standards specify TTY requirements for public buildings that are different than those required for private buildings. In order to maintain consistency in the requirements applicable to all its recipients, regardless of whether they are public or private entities, NASA is requiring all buildings and facilities covered by its section 504 Federally assisted rule to comply with the requirements for a "public building or facility," which are the requirements for buildings subject to title II of the ADA.

The NPRM proposes that compliance with the 2010 Standards is required one year from the publication date of the final rule in the **Federal Register**. In the period between the effective date of the final rule and the compliance date for new construction and alterations announced in the final rule, the NPRM proposes that recipients shall be permitted to choose to use the 2010

Standards in lieu of UFAS.² However, regardless of which accessibility standard recipients choose to use during this time period, recipients may not designate one accessibility standard for part of a facility and the other accessibility standard for the remainder.

The NPRM also proposes to adopt the approach used in both title II at 28 CFR 35.151(c) and title III at 28 CFR 36.406(a) to determine the "triggering event" for applying the proposed standards to new construction and alterations under section 504. For NASA recipients that are public entities (i.e., state and local governments and their agencies and organizations) who would otherwise comply with title II, the triggering event will be the commence of physical construction or alterations. For private entities who would otherwise comply with title III (i.e., privately owned and operated organizations), the triggering event is the date of: a) The last application for a building permit or permit extension certified to be complete by a state, county, or local government; or b) in those jurisdictions where the government does not certify completion of applications, the date when the last application for a building permit or permit extension is received by the State, county, or local government; or c) if no permit is required, the start of physical construction or alterations. For both public and private entities, NASA proposes to adopt the language found at 28 CFR 35.151(c)(4) in title II and 28 CFR 36.406(a)(4) in title III to make it clear that the date of ceremonial groundbreaking or the date a structure is razed to make it possible for construction of a facility to take place does not qualify as the commencement of physical construction.

Reasonable Accommodation (Non-Employment)

In *Southeastern Community College v. Davis*, 442 U.S. 397, 99 S.Ct. 2361 (1979), the Supreme Court held that a person is not protected by section 504 if, in order for the person to meet reasonable eligibility standards, the person needs program or policy modifications that would fundamentally alter the nature of the provider's program or impose undue financial and

² This choice is in keeping with the Department of Justice March 2011 memorandum advising Federal agencies that until such time as they update their agency's regulation implementing the Federally assisted provisions of section 504 of the Rehabilitation Act of 1973 (section 504), they may notify covered entities that they may use the 2010 ADA Standards for Accessible Design (2010 Standards) as an acceptable alternative to the Uniform Federal Accessibility Standards (UFAS). (www.ada.gov/504_memo_standards.htm).

administrative burdens (applicant who was denied admission to college nursing program because of her hearing disability asked college to provide hearing supervisor to aid her in communicating with patients, to dispense with certain required courses, and to train her to hold some, but not all, positions available to a registered nurse). Although the Court also opined in *Davis* that there may be situations where a refusal to modify an existing program might be discriminatory, this issue was posed to, and analyzed by, the Court in terms of the proper interpretation of the statutory term “otherwise qualified.” As a result, agency Section 504 regulations³ originally promulgated after the *Davis* decision addressed the obligation to provide reasonable accommodations/modifications in the definition section for “qualified handicapped person” (rather than in the nondiscrimination section).⁴

Subsequently, in *Alexander v. Choate*, 469 U.S. 287, 105 S.Ct. 712 (1985) (Medicaid recipients not entitled to relief under section 504 against state’s reduction in the number of inpatient hospital days that state Medicaid would pay), the Court clarified its *Davis* analysis. In that case, the Court described *Davis* as striking a balance between the need to provide qualified individuals with disabilities with meaningful access to the benefit the grantee offers and the legitimate interests of Federal grantees in preserving the integrity of their programs (469 U.S. at 300–301). It further stated that, although its opinion in *Davis* “addressed that portion of section 504 that requires that a handicapped individual be ‘otherwise qualified’ before the nondiscrimination principle of section 504 becomes relevant, . . . the question of who is ‘otherwise qualified’ and what actions constitute ‘discrimination’ under the section would seem to be two sides of a single coin; the ultimate question is the extent to which a grantee is required to make reasonable modifications [accommodations] in its programs for

the needs of the handicapped.” (469 U.S. at 300, note 19).

In addition, in keeping with these decisions of the Supreme Court over the past decades, Federal courts and Federal agencies have regularly acknowledged the affirmative obligation to provide qualified individuals with disabilities reasonable accommodations in programs, services, and activities.

Similarly, Congress, in the ADA at 42 U.S.C. 12182(b)(2)(A)(ii), and DOJ, in its ADA regulations at 28 CFR 35.130(b)(7) and 28 CFR 36.302, stated the obligation as a positive requirement to make reasonable changes in policies, practices, or procedures when necessary to avoid discrimination on the basis of disability. Accordingly, and with the approval of the DOJ pursuant to its section 504 coordination authority, we are proposing to add to the section 504 rule at §§ 1251.111 (Federally Assisted Programs) and 1251.581 (Federally Conducted Programs) a provision stating that a recipient must provide reasonable accommodations by making changes to policies, practices, or procedures when necessary to avoid discrimination on the basis of disability, unless the covered entity can show that the accommodations would result in a fundamental alteration in the nature of its service, program, or activity or impose undue financial and administrative burdens. The term “reasonable accommodation” is intended to have the same meaning as the term reasonable modifications under title II of the ADA (and the title II implementing regulation) and not the same meaning as “reasonable accommodation” in title I of the ADA (and the title I implementing regulation) covering employment. However, unlike reasonable modifications under title II, the obligation to provide reasonable accommodations under section 504 is limited by both the fundamental alteration and the undue financial and administrative burden defenses.

Qualified Individual With a Disability

NASA is proposing to revise § 1251.102(k) Qualified Individual with a Disability in order to streamline the language and update the references to employment to cite to the EEOC title I ADA regulation.

Direct Threat

In *School Bd. of Nassau County, Fla. v. Arline*, 480 U.S. 273, 107 S.Ct. 1123 (1987) (school board dismissed teacher after a third relapse of tuberculosis within a two-year period), the Court held that (i) section 504 covers individuals with contagious diseases and (ii) the determination of whether a

person with a contagious disease is otherwise qualified must be made on an individualized basis, taking into account the nature of the risk (how the disease is transmitted), duration of the risk (how long is the carrier infectious), severity of the risk (what is the potential harm to third parties), and probability the disease will be transmitted and will cause varying degrees of harm. The individualized inquiry must include appropriate findings of fact about these factors, based on reasonable medical judgments given the state of medical knowledge; based on these findings, a determination must be made as to whether the individual’s disability could be reasonably accommodated.⁵ This concept was incorporated by Congress into the ADA where it was termed a “direct threat.” The ADA regulations for titles II and III incorporate provisions allowing for determinations of “direct threat” in §§ 35.104 and 36.104 (definitions) and §§ 35.139 and 36.208. Accordingly, and with the approval of DOJ pursuant to its coordination authority under section 504, we are proposing to revise our section 504 regulation to include language addressing direct threat consistent with the language included in the ADA title II regulation. See proposed §§ 1251.110 (Federally Assisted Programs) and 1251.580 (Federally Conducted Programs).

Procedures for Compliance

Federal agencies that have the responsibility to ensure that their recipients comply with civil rights regulations that prohibit discrimination in programs, services, and activities that receive Federal financial assistance have provisions in their regulations that provide the authority for agencies to ensure compliance and conduct enforcement activities. NASA’s section 504 regulation at § 1251.400 incorporates by reference several provisions of the Title VI of the Civil Rights Act of 1964 regulation that authorize NASA to conduct compliance activities to ensure that recipients do not discriminate on the basis of disability in their programs, services, and activities. These provisions of the title VI regulation require NASA to conduct periodic compliance reviews of recipient programs; receive, investigate and resolve complaints of

³ See, e.g., 14 CFR 1251.503 (NASA’s section 504 Federally conducted regulation.)

⁴ With respect to any agency program or activity under which a person is required to perform services or to achieve a level of accomplishment, the regulatory definition of a “qualified handicapped person” (revised to “qualified individual with a disability” in this part) is an individual who meets the essential eligibility requirements of the program and who can achieve the purpose of the program or activity without modifications in the program or activity that the agency can demonstrate would result in a fundamental alteration in its nature.

⁵ While *Arline* speaks to “direct threat” in terms of allegations that an individual with a “contagious disease” may pose a danger to the health and safety of others, the individualized inquiry and the specific analysis required by *Arline* and this regulation applies to all allegations that a person with a disability poses a “direct threat” to the health or safety to others.

discrimination on the basis of disability alleged by recipient beneficiaries;⁶ conduct hearings to determine whether Federal financial assistance is to be suspended, revoked, or withheld due to a recipient's failure to comply with any provisions of section 504;⁷ and judicial review of NASA actions to enforce Section 504.⁸ However, the section 504 regulation does not incorporate by reference three additional title VI regulatory provisions that are included in other Federal agency section 504 regulations that pertain to procedures for compliance and are critical to effective enforcement of section 504. In contrast, NASA's civil rights regulations that prohibit discrimination on the basis of sex (Title IX of the Education Amendments of 1972)⁹ and age (Age Discrimination Act of 1975),¹⁰ as well as title VI, do have these provisions.

NASA proposes to amend its section 504 regulation at § 1251.400 to incorporate by reference those title VI regulatory provisions omitted from this section 504 Federally assisted regulation that are necessary for NASA to ensure that recipients and subrecipients are complying with this part. Accordingly, NASA will incorporate by reference into § 1251.400, NASA's title VI regulation at § 1250.105 (Compliance Information), which requires NASA to seek the cooperation of recipients in obtaining compliance with this part; requires recipients and subrecipients to keep records and provide reports to NASA upon request to determine compliance with this part; requires recipients to permit NASA to have access to records and sources of information to determine compliance with this part; and requires recipients to make available information regarding provisions of this part in a manner deemed appropriate by NASA to apprise interested persons of the rights and protections afforded to them by this part. NASA will also incorporate by reference into § 1251.400, NASA's title VI regulation at § 1250.107 (Procedures for Effecting Compliance), which delineates the process by which NASA will effectuate compliance with this part through the termination, suspension, or refusal to grant or continue Federal financial assistance if a recipient's noncompliance with this part cannot be remedied through informal means. Lastly, NASA will incorporate by reference into § 1251.400, NASA's title VI regulation at § 1250.109 (decisions and notices)

which delineates the process for rendering decisions and findings of the hearings conducted in accordance with § 1250.107.

NASA's Revisions to its Section 504 Regulation for Federally Conducted Programs

In addition to its proposed revisions to its section 504 Federally assisted regulation at § 1215.1, NASA is also proposing to revise its section 504 regulation that prohibits discrimination on the basis of disability in programs, services, and activities conducted by NASA at § 1251.5. In 1978, Congress extended application of section 504 to programs and activities conducted by Federal Executive agencies and the United States Postal Service. Pursuant to Executive Order 12250, the Department of Justice developed a prototype regulation to implement the 1978 amendment for Federally conducted programs and activities. More than 80 Federal agencies, including NASA, have now issued final regulations based on that prototype, prohibiting discrimination based on handicap in the programs and activities they conduct. Despite the large number of regulations implementing section 504 for Federally assisted and Federally conducted programs and activities, there is very little variation in their substantive requirements, or even in their language. The regulatory revisions in this rulemaking do not propose different requirements for NASA's Federally conducted programs, with the exception of the applicable accessibility standards for new and altered facilities.¹¹

Specifically, NASA proposes to revise the definition of "disability" and "individual with a disability" at § 1251.503 by incorporating by reference the companion definitions in the revised Federally assisted programs regulation at § 1251.102(h) and (k). NASA also proposes to revise the definition of "direct threat" and revise the regulatory standards for direct threat, employment, and reasonable accommodation in the Federally conducted programs regulation to conform with the companion regulatory standards for direct threat found at § 1251.110, employment found at

§ 1251.2, and reasonable accommodation found at § 1251.111. Lastly, NASA proposes to revise its Federally conducted programs regulation at § 1251.551 to update the regulatory reference to the GSA standards applicable to Federal buildings subject to the Architectural Barriers Act for new construction and alterations, which is no longer at GSA Federal Management Regulation 41 CFR 101-19.600 to 101-19.607, but is now found at 41 CFR part 102-76, subpart C.

Statutory Authority

The National Aeronautics and Space Act (the Space Act), 51 U.S.C. 20113 (a), authorizes the Administrator of the National Aeronautics and Space Administration (NASA) to make, promulgate, issue, rescind, and amend rules and regulations governing the manner of its operations and the exercise of the powers vested in it by law.

Regulatory Analysis

Executive Order 12866 and Executive Order 13563

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This proposed rule has been designated a "significant regulatory action," although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, this rule has been reviewed by the Office of Management and Budget.

Regulatory Flexibility Act

It has been certified that this rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act Statement

This rule does not contain an information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and Tribal governments, in the aggregate, or by the

⁶ 14 CFR 1250.106.

⁷ 14 CFR 1250.108.

⁸ 14 CFR 1250.110.

⁹ 14 CFR 1253.605.

¹⁰ 14 CFR subpart 1252.2.

¹¹ Facilities designed, built, or altered with Federal dollars or leased by Federal agencies are subject to the Architectural Barriers Act (ABA). The General Services Administration (GSA) is responsible for prescribing the accessibility standards for all of these facilities (other than residential structures and Department of Defense and U.S. Postal Service facilities). Thus, this rule will reference the updated ABA Accessibility Standards adopted by GSA in 2007. See 41 CFR part 102-76 Subpart C.

private sector, of \$100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996 (as amended), 5 U.S.C. 804. This rule will not result in an annual effect on the economy of

\$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 14 CFR Part 1251

Administrative practice and procedure, civil rights, equal employment opportunity, Federal buildings and facilities, and individuals with disabilities.

For the reasons stated in the preamble, the National Aeronautics and

Space Administration proposes to amend 14 CFR part 1251 as follows:

PART 1251—NONDISCRIMINATION ON BASIS OF DISABILITY

■ 1. The authority citation for part 1251 is revised to read as follows:

Authority: Sec. 504 (29 U.S.C. 794)

■ 2. Revise the heading of part 1251 to read as set forth above.

■ 3. Remove the following words wherever they appear in part 1251 and add in their place as indicated in the table below.

Remove	Add in its place
handicap	disability.
handicaps	disabilities.
handicapped person	individual with a disability.
handicapped persons	individuals with a disability.
handicapped individual	individual with a disability.
handicapped individuals	individuals with a disability.
individuals with handicaps	individuals with a disability.
qualified handicapped individual	qualified individual with a disability.
qualified handicapped individuals	qualified individuals with a disability.
qualified individuals with handicaps	qualified individuals with a disability.
qualified handicapped applicants or employees	qualified applicants or employees with a disability.
nonhandicapped persons	persons who do not have a disability.

Subpart 1251.1—General Provision

■ 4. Revise § 1251.100 to read as follows:

§ 1251.100 Purpose and broad coverage.

(a) *General.* This part effectuates Section 504 of the Rehabilitation Act of 1973, which is designed to eliminate discrimination on the basis of handicap in any program or activity receiving Federal financial assistance.

(b) *Broad coverage.* Consistent with the Americans with Disabilities Amendments Act of 2008 (ADAA) and its purpose of reinstating a broad scope of protection under the Americans with Disabilities Act and this part, the definition of disability in this chapter shall be construed in favor of broad coverage of individuals under this part, to the maximum extent permitted by the terms of this part.

■ 5. Amend § 1251.102 as follows:

■ a. In paragraph (c), remove the word “Assistant” and add in its place the word “Associate” wherever it occurs and add the words “Diversity and” after the word “for”;

■ b. In paragraph (d), remove the word “entry” and add in its place the word “entity”;

■ c. Revise paragraphs (h)(1)(iii) and (h)(2)(i) through (iv);

■ d. Add paragraphs (h)(2)(v) and (vi);

■ e. Revise paragraphs (i) and (j); and

■ f. Add paragraphs (l) through (m).
The revisions and additions read as follows:

§ 1251.102 Definitions.

* * * * *

(h) * * *

(1) * * *

(iii) Being regarded as having such an impairment as described in paragraph (h)(1)(v)(A) of this section. This means that the individual has been subjected to an action prohibited by this part because of an actual or perceived impairment that is not both “transitory and minor.”

(A) *Rules of construction* (1) An individual may establish coverage under any one or more of the three prongs of the definition of disability in this paragraph (h)(1), the “actual disability” prong in paragraph (h)(1)(i) of this section, the “record of” prong in paragraph (h)(1)(ii) of this section, or the “regarded as” prong in paragraph (h)(1)(iii) of this section.

(2) Where an individual is not challenging a recipient’s failure to provide reasonable accommodations under § 1251.111, it is generally unnecessary to proceed under the “actual disability” or “record of” prongs, which require a showing of an impairment that substantially limits a

major life activity or a record of such an impairment. In these cases, the evaluation of coverage can be made solely under the “regarded as” prong of the definition of disability, which does not require a showing of an impairment that substantially limits a major life activity or a record of such an impairment. An individual may choose, however, to proceed under the “actual disability” or “record of” prong regardless of whether the individual is challenging a public entity’s failure to provide reasonable accommodations.

(B) [Reserved]

(2) * * *

(i) *Physical or mental impairment* means:

(A) Any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more of the following body systems:

Neurological, musculoskeletal, special sense organs, respiratory (including speech organs), cardiovascular, reproductive, digestive, genitourinary, immune, circulatory, hemic and lymphatic, skin, and endocrine; or

(B) Any mental or psychological disorder such as an intellectual disability, organic brain syndrome, emotional or mental illness, and specific learning disabilities. The phrase “physical or mental impairment”

includes, but is not limited to, such contagious and noncontagious diseases and conditions as orthopedic, visual, speech and hearing impairments, cerebral palsy, epilepsy, muscular dystrophy, multiple sclerosis, cancer, heart disease, diabetes, intellectual disability, emotional illness, specific learning disabilities (including but not limited to dyslexia), HIV disease (whether symptomatic or asymptomatic), tuberculosis, drug addiction, and alcoholism.

(C) The phrase “physical or mental impairment” does not include homosexuality or bisexuality.

(ii) *Major life activities* include, but are not limited to:

(A) Caring for oneself, performing manual tasks, seeing, hearing, eating, sleeping, walking, standing, sitting, reaching, lifting, bending, speaking, breathing, learning, reading, concentrating, thinking, communicating, interacting with others, and working; and

(B) The operation of a major bodily function, including functions of the immune system, special sense organs and skin; normal cell growth; and digestive, genitourinary, bowel, bladder, neurological, brain, respiratory, circulatory, cardiovascular, endocrine, hemic, lymphatic, musculoskeletal, and reproductive functions. The operation of a major bodily function includes the operation of an individual organ within a body system.

(C) In determining other examples of major life activities, the term “major” shall not be interpreted strictly to create a demanding standard for disability. Whether an activity is a “major life activity” is not determined by reference to whether it is of “central importance to daily life.”

(iii) *Substantially limits*—(A) *Rules of construction*. The following rules of construction apply when determining whether an impairment substantially limits an individual in a major life activity.

(1) The term “substantially limits” shall be construed broadly in favor of expansive coverage, to the maximum extent permitted by the terms of the ADA Amendments Act of 2008. “Substantially limits” is not meant to be a demanding standard.

(2) An impairment is a disability within the meaning of this part if it substantially limits the ability of an individual to perform a major life activity as compared to most people in the general population. An impairment need not prevent, or significantly or severely restrict, the individual from performing a major life activity in order to be considered substantially limiting.

(3) The primary object of attention in cases brought under section 504 should be whether recipients have complied with their obligations and whether discrimination has occurred, not the extent to which an individual’s impairment substantially limits a major life activity. Accordingly, the threshold issue of whether an impairment substantially limits a major life activity should not demand extensive analysis.

(4) The determination of whether an impairment substantially limits a major life activity requires an individualized assessment. However, in making this assessment, the term “substantially limits” shall be interpreted and applied to require a degree of functional limitation that is lower than the standard for substantially limits applied prior to the ADA Amendments Act.

(5) The comparison of an individual’s performance of a major life activity to the performance of the same major life activity by most people in the general population usually will not require scientific, medical, or statistical evidence. Nothing in this paragraph is intended, however, to prohibit or limit the use of scientific, medical, or statistical evidence in making such a comparison where appropriate.

(6) The determination of whether an impairment substantially limits a major life activity shall be made without regard to the ameliorative effects of mitigating measures. However, the ameliorative effects of ordinary eyeglasses or contact lenses shall be considered in determining whether an impairment substantially limits a major life activity. Ordinary eyeglasses or contact lenses are lenses that are intended to fully correct visual acuity or to eliminate refractive errors.

(7) An impairment that is episodic or in remission is a disability if it would substantially limit a major life activity when active.

(8) An impairment that substantially limits one major life activity need not substantially limit other major life activities in order to be considered a substantially limiting impairment.

(9) The six-month “transitory” part of the “transitory and minor” exception in paragraph (h)(3) of this section does not apply to the “actual disability” or “record of” prongs of the definition of disability. The effects of an impairment lasting or expected to last fewer than six months can be substantially limiting within the meaning of this section for establishing an actual disability or a record of a disability.

(B) *Predictable assessments*. (1) The principles set forth in § 1251.102(h)(2)(iii) are intended to provide for more generous coverage and

application of section 504’s prohibition on discrimination through a framework that is predictable, consistent, and workable for all individuals and entities with rights and responsibilities under section 504.

(2) Applying the principles set forth in § 1251.102(h)(2)(iii) the individualized assessment of some types of impairments will, in virtually all cases, result in a determination of coverage under § 1251.102(h)(1)(i) (the “actual disability” prong) or § 1251.102(h)(1)(ii) (the “record of” prong). Given their inherent nature, these types of impairments will, as a factual matter, virtually always be found to impose a substantial limitation of a major life activity. Therefore, with respect to these types of impairments, the necessary individualized assessment should be particularly simple and straightforward.

(3) For example, applying the principles set forth in § 1251.102(h)(2)(iii) it should easily be concluded that the following types of impairments will, at a minimum, substantially limit the major life activities indicated:

(i) Deafness substantially limits hearing and auditory function;

(ii) Blindness substantially limits visual function;

(iii) An intellectual disability substantially limits reading, learning, and problem solving;

(iv) Partially or completely missing limbs or mobility impairments requiring the use of a wheelchair substantially limit musculoskeletal function;

(v) Autism substantially limits learning, social interaction, and communication;

(vi) Cancer substantially limits normal cell growth;

(vii) Cerebral palsy substantially limits brain function;

(viii) Diabetes substantially limits endocrine function;

(ix) Epilepsy, muscular dystrophy, and multiple sclerosis substantially limit neurological function;

(x) Human Immunodeficiency Virus (HIV) infection substantially limits immune function; and

(xi) Major depressive disorder, bipolar disorder, post-traumatic stress disorder, traumatic brain injury, obsessive compulsive disorder, and schizophrenia substantially limit brain function. The types of impairments described in this paragraph may substantially limit additional major life activities not explicitly listed above.

(C) *Condition, manner or duration*. (1) At all times taking into account the principles in § 1251.102(h)(2)(iii), in determining whether an individual is

substantially limited in a major life activity, it may be useful in appropriate cases to consider, as compared to most people in the general population, the conditions under which the individual performs the major life activity; the manner in which the individual performs the major life activity; or the duration of time it takes the individual to perform the major life activity, or for which the individual can perform the major life activity.

(2) Consideration of facts such as condition, manner, or duration may include, among other things, consideration of the difficulty, effort or time required to perform a major life activity; pain experienced when performing a major life activity; the length of time a major life activity can be performed; or the way an impairment affects the operation of a major bodily function. In addition, the non-ameliorative effects of mitigating measures, such as negative side effects of medication or burdens associated with following a particular treatment regimen, may be considered when determining whether an individual's impairment substantially impairs a major life activity.

(3) In determining whether an individual has a disability under the "actual disability" or "record of" prongs of the definition of disability, the focus is on how a major life activity is substantially limited, not on what outcomes an individual can achieve. For example, someone with a learning disability may achieve a high level of academic success, but may nevertheless be substantially limited in one or more major life activities, including, but not limited to, reading, writing, speaking, or learning because of the additional time or effort he or she must spend to read, write, speak, or learn compared to most people in the general population.

(D) Mitigating measures include, but are not limited to:

(1) Medication, medical supplies, equipment, appliances, low-vision devices (defined as devices that magnify, enhance, or otherwise augment a visual image, but not including ordinary eyeglasses or contact lenses), prosthetics including limbs and devices, hearing aid(s) and cochlear implant(s) or other implantable hearing devices, mobility devices, and oxygen therapy equipment and supplies.

(2) Use of assistive technology;

(3) Reasonable accommodations or auxiliary aids or services as defined in this section;

(4) Learned behavioral or adaptive neurological modifications; or

(5) Psychotherapy, behavioral therapy, or physical therapy.

(iv) *Has a record of such an impairment* means:

(A) *Broad construction.* Whether an individual has a record of an impairment that substantially limited a major life activity shall be construed broadly to the maximum extent permitted by section 504 and should not demand extensive analysis. An individual will be considered to fall within this prong of the definition of disability if the individual has a history of an impairment that substantially limited one or more major life activities when compared to most people in the general population, or was misclassified as having had such an impairment. In determining whether an impairment substantially limited a major life activity, the principles articulated in § 1251.102(h)(2)(iii) apply.

(B) Reasonable accommodation. An individual with a record of a substantially limiting impairment may be entitled to a reasonable accommodation if needed and related to the past disability.

(v) *Regarded as having such an impairment* means:

(A) An individual is "regarded as having such an impairment" if the individual is subjected to an action prohibited by the ADA because of an actual or perceived physical or mental impairment, whether or not that impairment substantially limits, or is perceived to substantially limit, a major life activity, except for an impairment that is both transitory and minor. A transitory impairment is an impairment with an actual or expected duration of six months or less.

(B) An individual is "regarded as having such an impairment" any time a covered entity takes a prohibited action against the individual because of an actual or perceived impairment, even if the entity asserts, or may or does ultimately establish, a defense to such action.

(C) Establishing that an individual is "regarded as having such an impairment" does not, by itself, establish liability. Liability is established under section 504 only when an individual proves that a covered entity discriminated on the basis of disability within the meaning of section 504.

(vi) *Exclusions.* The term "disability" does not include:

(A) Transvestism, transsexualism, pedophilia, exhibitionism, voyeurism, gender identity disorders not resulting from physical impairments, or other sexual behavior disorders;

(B) Compulsive gambling, kleptomania, or pyromania; or

(C) Psychoactive substance use disorders resulting from current illegal use of drugs.

* * * * *

(i) *Qualified individual with a disability* means:

(1) With respect to any aid, benefit, or service, provided under a program or activity subject to this part, an individual with a disability who, with or without reasonable accommodations in rules policies, or procedures, the removal of architectural, communication, or transportation barriers, or the provision auxiliary aids or services, meets the essential eligibility requirements for participation in, or receipt from, that aid, benefit, or service, and

(2) With respect to employment, the definition given that term in the Equal Employment Opportunity Commission's regulation at 29 CFR part 1630, implementing Title I of the Americans with Disabilities Act of 1990, which regulation is made applicable to this part by § 1251.2.

(j) *Disability* means a physical or mental impairment which substantially limits one or more major life activities as defined in paragraph (h) of this section.

* * * * *

(l) *Direct threat* means a significant risk to the health or safety of others that cannot be eliminated by a change to policies, practices or procedures, or by the provision of auxiliary aids or services as provided in § 1251.110 of this part.

(m) *Auxiliary aids and services* means services or devices that enable persons with sensory, manual, or speech disabilities to have an equal opportunity to participate in, and enjoy the benefits of, programs or activities conducted by the recipient. Auxiliary aids and services include:

(1) Qualified interpreters onsite or through video remote interpreting (VRI) services; notetakers; real-time computer-aided transcription services; written materials; exchange of written notes; telephone handset amplifiers; assistive listening devices; assistive listening systems; telephones compatible with hearing aids; closed caption decoders; open and closed captioning, including realtime captioning; voice, text, and video-based telecommunications products and systems, including text telephones (TTYs), videophones, and captioned telephones, or equally effective telecommunications devices; videotext displays; accessible electronic and information technology; or other effective methods of making aurally delivered information available to

individuals who are deaf or hard of hearing;

(2) Qualified readers; taped texts; audio recordings; Brailled materials and displays; screen reader software; magnification software; optical readers; secondary auditory programs (SAP); large print materials; accessible electronic and information technology; or other effective methods of making visually delivered materials available to individuals who are blind or have low vision;

(3) Acquisition or modification of equipment or devices; and

(4) Other similar services and actions.

§ 1251.104 [Amended]

■ 6. In § 1251.104, in paragraphs (a) and (c)(3), remove the word “Assistant” and add in its place the word “Associate”.

§ 1251.105 [Amended]

■ 7. In paragraphs (a)(1) through (3) and (c)(2) introductory text, remove the word “Assistant” wherever it appears and add in its place the word “Associate”.

■ 8. Amend § 1251.107 by revising paragraph (a) to read as follows:

§ 1251.107 Notice.

(a) A recipient that employs 15 or more persons shall take appropriate initial and continuing steps to notify participants, beneficiaries, applicants, and employees, including those with vision or hearing disabilities, and unions or professional organizations holding collective bargaining or professional agreements with the recipient that it does not discriminate on the basis of disability in violation of section 504 and this part. The notification shall state, where appropriate, that the recipient does not discriminate in admission or access to, or treatment or employment in, its programs or activities. The notification shall also include an identification of the responsible employee designated pursuant to § 1251.106(a). A recipient shall make the initial notification required by this paragraph within 90 days of the effective date of this part. Methods of initial and continuing notification may include the posting of notices, transmission via electronic mail or text message, publication on the recipient's internet Web site, or in newspapers and magazines, placement of notices in recipient's publication, and distribution of memoranda or other written communications.

* * * * *

§ 1251.108 [Amended]

■ 9. Amend § 1251.108 by removing the word “Assistant” wherever it appears

and adding in its place the word “Associate”.

■ 10. Add § 1251.110 to subpart 1251.1 to read as follows:

§ 1251.110 Direct threat.

(a) This part does not require a recipient to permit an individual to participate in or benefit from the services, programs, or activities of that recipient when that individual poses a direct threat to the health or safety of others.

(b) In determining whether an individual poses a direct threat to the health or safety of others, a recipient must make an individualized assessment, based on reasonable judgment that relies on current medical knowledge or on the best available objective evidence, to ascertain: the nature, duration, and severity of the risk; the probability that the potential injury will actually occur; and whether reasonable accommodations in policies, practices, or procedures or the provision of auxiliary aids or services will mitigate the risk.

■ 11. Add § 1251.111 to subpart 1251.1 to read as follows:

§ 1251.111 Reasonable accommodation.

A recipient shall make reasonable accommodations in policies, practices, or procedures when such accommodations are necessary to avoid discrimination on the basis of disability, unless the recipient can demonstrate that making the accommodations would fundamentally alter the nature of the service, program, or activity or result in an undue financial and administrative burden. For the purposes of this section, the term reasonable accommodation shall be interpreted in a manner consistent with the term “reasonable modifications” as set forth in the Americans with Disabilities Act Title II regulation at 28 CFR 35.130(b)(7), and not as it is defined or interpreted for the purposes of employment discrimination under Title I of the ADA (42 U.S.C. 12111–12112) and its implementing regulation at 29 CFR Part 1630.

■ 12. Add § 1251.112 to subpart 1251.1 to read as follows:

§ 1231.112 Communications.

(a) A recipient shall take appropriate steps to ensure effective communication with applicants, participants, and members of the public.

(1) The recipient shall furnish appropriate auxiliary aids or services where necessary to afford an individual with a disability, including applicants, participants and members of the public, an equal opportunity to participate in, and enjoy the benefits of, a program or activity of the recipient.

(i) In determining what type of auxiliary aid or service is necessary, the recipient shall give primary consideration to the requests of the individual with a disability.

(ii) The recipient need not provide individually prescribed devices, readers for personal use or study, or other devices of a personal nature.

(2) Where the recipient communicates with applicants and beneficiaries by telephone, telecommunication devices for deaf persons (TTY's) or equally effective telecommunication systems shall be used to communicate with persons with hearing disabilities.

(b) The recipient shall ensure that interested persons, including persons with vision or hearing disabilities, can obtain information as to the existence and location of accessible services, activities, and facilities.

(c) This section does not require the recipient to take any action that it can demonstrate would result in a fundamental alteration in the nature of a program or activity or in undue financial and administrative burdens. In those circumstances where the recipient believes that the proposed action would fundamentally alter the program or activity or would result in undue financial and administrative burdens, the recipient has the burden of proving that compliance with § 1251.112 would result in such alteration or burdens. The decision that compliance would result in such alteration or burdens must be made by the recipient agency head or his or her designee after considering all of the recipient's resources available for use in the funding and operation of the conducted program or activity and must be accompanied by a written statement of the reasons for reaching that conclusion. If an action required to comply with this section would result in such an alteration or such burdens, the recipient shall take any other action that would not result in such an alteration or such burdens but would nevertheless ensure that, to the maximum extent possible, individuals with disabilities receive the benefits and services of the program or activity.

■ 13. Revise § 1251.200 to read as follows:

§ 1251.200 Discrimination prohibited.

(a) *General.* No qualified individual with a disability shall, on the basis of disability, be subjected to discrimination in employment under any program or activity to which this part applies.

(b) *Employment discrimination standards.* The standards used to determine whether paragraph (a) of this section has been violated shall be the

standards applied under Title I of the Americans with Disabilities Act of 1990 (42 U.S.C. 12111 *et seq.*) and, as such sections relate to employment, the provisions of sections 501 through 504 and 510 of the Americans with Disabilities Act of 1990 (42 U.S.C. 12201–12204 and 12210), as amended by the ADA Amendments Act of 2008 (Pub. L. 110–325), as such standards are implemented in the Equal Employment Opportunity Commission’s regulation at 29 CFR part 1630, as amended. The procedures to be used to determine whether paragraph (a) of this section has been violated shall be the procedures set forth in § 1251.400 of this part.

§ 1251.202 [Amended]

■ 14. Amend § 1251.202 by removing the word “Assistant” in paragraph (a)(2) and adding in its place the word “Associate”.

■ 15. Amend § 1251.302 as follows:

■ a. Revise paragraphs (a) and (c)(1); and

■ b. Redesignate paragraphs (c)(2) and (3) as paragraphs (c)(5) and (6) and add new paragraphs (c)(2) through (4).

■ The revisions and additions read as follows:

§ 1251.302 New construction and alterations.

(a) *Design and construction.* Each facility or part of a facility constructed by, on behalf of, or for the use of a recipient shall be designed and constructed in such manner that the facility or part of the facility is readily accessible to and usable by individuals with disabilities.

* * * * *

(c) *Accessibility standards and compliance dates—*(1) *New Construction and alterations by*

recipients that are private entities. (i) New construction and alterations in which the last application for a building permit or permit extension for such construction or alterations is certified to be complete by a state, county, or local government (or, in those jurisdictions where the government does not certify completion of applications, if the date when the last application for a building permit or permit extension is received by the state, county, or local government) is prior to [DATE ONE YEAR AFTER PUBLICATION OF THE FINAL RULE IN THE **Federal Register**], or if no permit is required, if the start of physical construction or alterations occurs prior to [DATE ONE YEAR FROM THE PUBLICATION OF THE FINAL RULE IN THE **Federal Register**], then such new construction and alterations must comply with either the Uniform Federal Accessibility Standards (UFAS) or the ADA Standards for Accessible Design, (2010 Standards) as defined in 28 CFR 35.104. Departures from particular requirements of either standard by the use of other methods shall be permitted when it is clearly evident that equivalent access to the facility or part of the facility is thereby provided.

(ii) New construction and alterations in which the last application for a building permit or permit extension for such construction or alterations is certified to be complete by a state, county, or local government (or, in those jurisdictions where the government does not certify completion of applications, if the date when the last application for a building permit or permit extension is received by the state, county, or local government) is on

or after [DATE ONE YEAR AFTER PUBLICATION OF THE FINAL RULE IN THE **Federal Register**], or if no permit is required, if the start of physical construction or alterations occurs on or after [DATE ONE YEAR FROM THE PUBLICATION OF THE FINAL RULE IN THE **Federal Register**], then such new construction and alterations shall comply with the 2010 Standards.

(2) *New construction and alterations by recipients that are public entities.* (i) If physical construction or alterations commence prior to [DATE ONE YEAR AFTER PUBLICATION OF THE FINAL RULE IN THE **Federal Register**], then such new construction and alterations must comply with either UFAS or the 2010 Standards as defined in 28 CFR 35.104. Departures from particular requirements of either standard by the use of other methods shall be permitted when it is clearly evident that equivalent access to the facility or part of the facility is thereby provided.

(ii) If physical construction or alterations commence on or after [DATE ONE YEAR AFTER PUBLICATION OF THE FINAL RULE IN THE **Federal Register**], then such new construction and alterations shall comply with the 2010 Standards.

(3) For the purposes of this section, ceremonial groundbreaking or razing of structures prior to site preparation will not be considered to commence or start physical construction or alterations.

(4) All newly constructed or altered buildings or facilities subject to this section shall comply with the requirements for a “public building or facility” as defined in section 106.5 of the 2010 Standards.

TABLE OF APPLICABLE STANDARDS FOR COMPLYING WITH 14 CFR 1251.302(c)

Compliance dates for new construction and alterations	Applicable standards for complying with 14 CFR 1251.302(c)
Prior to [DATE ONE YEAR AFTER PUBLICATION OF THE FINAL RULE IN THE Federal Register].	UFAS or the requirements for a “public building or facility” as defined in section 106.5 of the 2010 Standards
On or after [DATE ONE YEAR AFTER PUBLICATION OF THE FINAL RULE IN THE Federal Register].	All buildings or facilities shall comply with the requirements for a “public building or facility” as defined in section 106.5 of the 2010 Standards.

* * * * *

■ 16. Section 1251.400 is revised to read as follows:

§ 1251.400 Procedures for compliance.

(a) The investigative, compliance, and enforcement procedural provisions of Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d) are hereby adopted and apply to these section 504 regulations. These procedures are found at §§ 1250.105 through 1250.110 of this chapter.

(b) The agency shall ensure that complaints alleging violations of section 504 with respect to employment are processed according to the procedures established by the EEOC in 29 CFR part 1640 and the United States DOJ at 28 CFR part 37.

Subpart 1251.5—Enforcement of Nondiscrimination on the Basis of Disability in Programs or Activities Conducted by the National Aeronautics and Space Administration

■ 17. Section 1251.503 is revised to read as follows:

§ 1251.503 Definitions.

As used in this part, the term:

Assistant Attorney General means the Assistant Attorney General, Civil Rights

Division, United States Department of Justice.

Auxiliary aids and services means services or devices that enable persons with sensory, manual, or speech disabilities to have an equal opportunity to participate in, and enjoy the benefits of, programs or activities conducted by the agency. Auxiliary aids and services include:

(1) Qualified interpreters onsite or through VRI services; notetakers; real-time computer-aided transcription services; written materials; exchange of written notes; telephone handset amplifiers; assistive listening devices; assistive listening systems; telephones compatible with hearing aids; closed caption decoders; open and closed captioning, including realtime captioning; voice, text, and video-based telecommunications products and systems, including text telephones (TTYs), videophones, and captioned telephones, or equally effective telecommunications devices; videotext displays; accessible electronic and information technology; or other effective methods of making aurally delivered information available to individuals who are deaf or hard of hearing;

(2) Qualified readers; taped texts; audio recordings; Brailled materials and displays; screen reader software; magnification software; optical readers; secondary auditory programs (SAP); large print materials; accessible electronic and information technology; or other effective methods of making visually delivered materials available to individuals who are blind or have low vision;

(3) Acquisition or modification of equipment or devices; and

(4) Other similar services and actions.

Complete complaint means a written statement that contains the complainant's name and address and describes the agency's alleged discriminatory action in sufficient detail to inform the agency of the nature and date of the alleged violation of section 504. It shall be signed by the complainant or by someone authorized to do so on his or her behalf. Complaints filed on behalf of classes or third parties shall describe or identify (by name, if possible) the alleged victims of discrimination.

Direct threat means a significant risk to the health or safety of others that cannot be eliminated by a change to policies, practices or procedures, or by the provision of auxiliary aids or services as provided in § 1251.110 of this part.

Facility means all or any portion of buildings, structures, equipment, roads,

walks, parking lots, rolling stock or other conveyances, or other real or personal property.

Historic preservation programs means programs conducted by the agency that have preservation of historic properties as a primary purpose.

Historic properties means those properties that are listed or eligible for listing in the National Register of Historic Places or properties designated as historic under a statute of the appropriate state or local government body.

Individual with a disability means any person who meets the definition of "individual with a disability" under § 1251.102(h) of this part.

Qualified individual with a disability means any person who meets the definition of "qualified individual with a disability" under § 1251.102(k) of this part.

Section 504 means section 504 of the Rehabilitation Act of 1973 (Pub. L. 93–112, 87 Stat. 394 (29 U.S.C. 794)), as amended by the Rehabilitation Act Amendments of 1974 (Pub. L. 93–516, 88 Stat. 1617); the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978 (Pub. L. 95–602, 92 Stat. 2955); and the Rehabilitation Act Amendments of 1986 (Pub. L. 99–506, 100 Stat. 1810).

Substantial impairment means a significant loss of the integrity of finished materials, design quality, or special character resulting from a permanent alteration.

■ 18. Revise § 1251.540 to read as follows:

§ 1251.540 Employment.

(a) *General.* No qualified individual with a disability shall, on the basis of disability, be subjected to discrimination in employment under any program or activity to which this part applies.

(b) *Employment discrimination standards.* The standards used to determine whether paragraph (a) of this section has been violated shall be the standards applied under Title I of the Americans with Disabilities Act of 1990 (42 U.S.C. 12,111 *et seq.*) and, as such sections relate to employment, the provisions of sections 501 through 504 and 510 of the Americans with Disabilities Act of 1990 (42 U.S.C. 12201–12204 and 12210), as amended by the ADA Amendments Act of 2008 (Pub. L. 110–325), as such standards are implemented in the Equal Employment Opportunity Commission's regulation at 29 CFR part 1630, as amended.

■ 19. Revise § 1251.551 to read as follows:

§ 1251.551 Program accessibility: New construction and alterations.

Each building or part of a building that is constructed or altered by, on behalf of, or for the use of the agency shall be designed, constructed, or altered so as to be readily accessible to and usable by individuals with handicaps. The definitions, requirements, and standards of the Architectural Barriers Act (42 U.S.C. 4151–4157), as established in 41 CFR part 102–76, subpart C, apply to buildings covered by this section.

■ 20. In § 1251.570, revise paragraphs (b) and (c) to read as follows:

§ 1251.570 Compliance procedures.

* * * * *

(b) The agency shall process complaints alleging violations of section 504 with respect to employment according to the procedures established by the Equal Employment Opportunity Commission in 29 CFR part 1614.

(c) The Associate Administrator for Diversity and Equal Opportunity shall be responsible for coordinating implementation of this section. Complaints may be sent to the Office of Diversity and Equal Opportunity, NASA Headquarters, 300 E Street SW., Washington, DC 20546.

* * * * *

■ 21. Add § 1251.580 to subpart 1251.5 to read as follows:

§ 1251.580 Direct threat.

(a) This part does not require the Agency to permit an individual to participate in or benefit from the services, programs, or activities of that recipient when that individual poses a direct threat to the health or safety of others.

(b) In determining whether an individual poses a direct threat to the health or safety of others, a recipient must make an individualized assessment, based on reasonable judgment that relies on current medical knowledge or on the best available objective evidence, to ascertain: the nature, duration, and severity of the risk; the probability that the potential injury will actually occur; and whether reasonable accommodations in policies, practices, or procedures or the provision of auxiliary aids or services will mitigate the risk.

■ 22. Add § 1251.581 to subpart 1251.5 to read as follows:

§ 1251.581 Reasonable accommodation.

The agency shall make reasonable accommodations in policies, practices, or procedures when such accommodations are necessary to avoid discrimination on the basis of disability,

unless the recipient can demonstrate that making the accommodations would fundamentally alter the nature of the service, program, or activity or result in an undue financial and administrative burden. For the purposes of this section, the term “reasonable accommodation” shall be interpreted in a manner consistent with the term “reasonable modifications” as set forth in the Americans with Disabilities Act Title II regulation at 28 CFR 35.130(b)(7), and not as it is defined or interpreted for the purposes of employment discrimination under Title I of the ADA (42 U.S.C. 12111–12112) and its implementing regulations at 29 CFR part 1630.

Cheryl E. Parker,

NASA Federal Register Liaison Officer.

[FR Doc. 2014–26543 Filed 11–12–14; 8:45 am]

BILLING CODE 7510–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 801

[REG–138605–13]

RIN 1545–BL88

Balanced System for Measuring Organizational and Employee Performance Within the Internal Revenue Service

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulation.

SUMMARY: In the Rules and Regulations section of this issue of the **Federal Register**, the IRS and the Treasury Department are issuing a temporary regulation modifying the regulations governing the IRS Balanced System for Measuring Organizational and Employee Performance. The section being modified, Employee satisfaction measures, collects information from employees to measure and report on employee satisfaction. The temporary regulation provides for the reporting of this information to a higher agency level, to be consistent with other government-wide employee satisfaction surveys. The text of the temporary regulation serves as the text of the proposed regulation.

DATES: Written or electronic comments and requests for a public hearing must be received by January 12, 2015.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–138605–13), Internal Revenue Service, Room 5203,

P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–138605–13), Courier’s Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224; or sent electronically via the Federal eRulemaking Portal at <http://www.regulations.gov> (IRS–REG–138605–13).

FOR FURTHER INFORMATION CONTACT:

Concerning the proposed regulation, Neil Worden, (202) 317–5775; concerning submissions of comments, Oluwafunmilayo (Funmi) Taylor, Publications and Regulations Branch, (202) 317–6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

The temporary regulation published in the Rules and Regulations section of this issue of the **Federal Register** amends 26 CFR part 801 to permit the reporting of information collected to measure employee satisfaction to a higher agency level than the regulation currently allows. The Explanation of Provisions section of the temporary regulation explains the purpose of the temporary regulation and this proposed regulation.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulation does not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for a Public Hearing

Before this proposed regulation is adopted as a final regulation, consideration will be given to any written or electronic comments that are timely submitted to the IRS. The IRS and the Treasury Department request comments on all aspects of the proposed regulations. All comments will be available for public inspection and

copying. A public hearing may be scheduled if requested by any person who timely submits comments. If a public hearing is scheduled, notice of the date, time and place for the hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these regulations is Karen F. Keller, Office of Associate Chief Counsel (General Legal Services). However, other personnel from the IRS participated in their development.

List of Subjects in 26 CFR Part 801

Federal employees, Organization and functions (Government agencies).

Proposed Amendment to the Regulations

Accordingly, 26 CFR Part 801 is proposed to be amended as follows:

PART 801—BALANCED SYSTEM FOR MEASURING ORGANIZATIONAL AND EMPLOYEE PERFORMANCE WITHIN THE INTERNAL REVENUE SERVICE

■ **Paragraph 1.** The authority citation for part 801 continues to read in part as follows:

Authority: 5 U.S.C. 9501 * * *

■ **Par. 2.** Section 801.5 is amended to read as follows:

§ 801.5 [The text of the proposed amendment to § 801.5 is the same as the text of § 801.5T published elsewhere in this issue of the **Federal Register**].

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2014–26781 Filed 11–12–14; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 948

[SATS No.: WV–122–FOR; Docket ID: OSMRE–2013–0011; S1D1SSS08011000 SX066A00067F144S180110; S2D2SSS08011000SX066A00033 F14XS01520]

West Virginia Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSMRE), Interior.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: We are reopening the public comment period on a proposed

amendment to the West Virginia permanent regulatory program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). The proposed amendment consists of a Special Reclamation Tax Credit Rule that was submitted to OSMRE on August 7, 2014. The purpose of this document is to provide the public 15 additional days to comment on the proposed amendment.

DATES: The comment period for the proposed rule published on May 20, 2014, at 79 FR 28858–28860 is reopened. We will accept written comments on this amendment and the Special Reclamation Tax Credit Rule being announced today until 4:00 p.m. EDT, on November 28, 2014.

ADDRESSES: You may submit comments by any of the following two methods: Federal eRulemaking Portal: <http://www.regulations.gov>. The proposed rule has been assigned Docket ID OSM–2013–0011. If you would like to submit comments through the Federal eRulemaking Portal, go to <http://www.regulations.gov> and follow the instructions.

Mail/hand Delivery: Mr. Roger W. Calhoun, Director, Charleston Field Office, Office of Surface Mining Reclamation and Enforcement, 1027 Virginia Street, East, Charleston, West Virginia 25301.

Please include the rule identifier (WV–122–FOR) with your written comments.

Instructions: All submissions received must include the agency Docket ID (OSMRE–2013–0011) for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see “IV. Public Comment Procedures” in the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: The proposed rule and any comments that are submitted may be viewed over the internet at <http://www.regulations.gov>. Look for Docket ID OSMRE–2013–0011. In addition, you may review copies of the West Virginia program, this amendment, and all written comments received in response to this document at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. You may also receive one free copy of this amendment by contacting OSMRE’s Charleston Field Office listed below.

Mr. Roger W. Calhoun, Director,
Charleston Field Office, Office of
Surface Mining Reclamation and
Enforcement, 1027 Virginia Street,
East, Charleston, West Virginia 25301,

Telephone: (304) 347–7158, Email:
chfo@osmre.gov.

In addition, you may review a copy of the amendment during regular business hours at the following locations:

Morgantown Area Office, Office of
Surface Mining Reclamation and
Enforcement, 604 Cheat Road, Suite
150, Morgantown, West Virginia
26508, Telephone: (304) 291–4004.
(By Appointment Only)
Beckley Area Office, Office of Surface
Mining Reclamation and
Enforcement, 313 Harper Park Drive,
Suite 3, Beckley, West Virginia 25801,
Telephone: (304) 255–5265.

FOR FURTHER INFORMATION CONTACT: Mr.
Roger W. Calhoun, Director, Charleston
Field Office, Telephone: (304) 347–
7158. Email: chfo@osmre.gov.

SUPPLEMENTARY INFORMATION:

- I. Background on the West Virginia Program
- II. Description and Submission of the
Proposed Amendment
- III. Description of OSMRE’s Proposed Action
- IV. Public Comment Procedures
- V. Procedural Determinations

I. Background on the West Virginia Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, “. . . a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of the Act . . . ; and rules and regulations consistent with regulations issued by the Secretary pursuant to the Act.” See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the West Virginia program on January 21, 1981. You can find background information on the West Virginia program, including the Secretary’s findings, the disposition of comments, and conditions of approval of the West Virginia program in the January 21, 1981, **Federal Register** (46 FR 5915). You can also find later actions concerning West Virginia’s program and program amendments at 30 CFR 948.10, 948.12, 948.13, 948.15, and 948.16.

II. Description and Submission of the Proposed Amendment

On June 6, 2014, the West Virginia State Tax Department filed a Special Reclamation Tax Credit Rule with the Secretary of State to implement the special reclamation tax incentive revisions at West Virginia Code Section 22–3–11(g) and (h) for mine operators

who reclaim bond forfeiture sites within the State. The statutory revisions, as set forth in Committee Substitute for House Bill 2352, were previously announced in the May 20, 2014, **Federal Register** (79 FR 28858–28860). On August 7, 2014, the West Virginia Department of Environmental Protection (WVDEP) submitted the proposed rule to OSMRE at a meeting of the Special Reclamation Fund Advisory Council (Administrative Record Number WV–1597). The purpose of this notice is to provide the public an additional 15 days to review and comment on the proposed amendment announced in the **Federal Register** on May 20, 2014, at 79 FR 28858–28860 and the Special Reclamation Tax Credit Rule being announced today.

III. Description of OSMRE’s Proposed Action

1. CSR 110–29–1–6 Special Reclamation Tax Credit

This rule further clarifies and implements the proposed revisions to West Virginia Code 22–3–11(g and h) relating to special reclamation tax incentives for mine operators who reclaim bond forfeiture sites. The new Special Reclamation Tax Credit regulations are set forth at the Code of State Regulations (CSR) 110–29–1 through 6.

Non-substantive additions at CSR 110–29–2 include definitions of “Act,” “Bond forfeited mine site,” “Secretary,” and “Tax Commissioner.”

CSR 110–29–1.5 clarifies that the special reclamation tax credit is only available to qualified operators for taxable years beginning on or after July 12, 2013.

Under the new tax credit rule at CSR 110–29–2.4, a qualified operator is any person that obtains a permit under the West Virginia Surface Coal Mining and Reclamation Act to mine coal and perform reclamation on a bond forfeited mine site and that qualifies for the special reclamation tax credit.

CSR 110–29–4 sets forth requirements governing the application for and the amount of the tax credit. Section 4 provides that a qualified operator may reclaim the bond forfeited mine site pursuant to either an Article 3 permit or a reclamation agreement. The amount of tax credit granted to the qualified operator is based on the amount of money that would have been spent from the Special Reclamation Fund and the Special Reclamation Water Trust Fund on the bond forfeited site as determined by the WVDEP Secretary.

CSR 110–29–5 specifies operator eligibility requirements for the tax credit and the limitation of the tax credit. A

qualified operator may use the tax credit to offset payment of or liability for the special reclamation tax for the tax year or carry it forward for use in future tax years until no credit is remaining.

CSR 110–29–6 contains general procedures to claim and administer the tax credit. The qualified operator must provide complete and accurate forms and other information to claim the tax credit. In addition, the qualified operator must maintain records to verify the validity of the tax credit and the amount of tax credit claimed. Finally, the Tax Commissioner has the authority to audit the qualified operator.

All of the proposed State tax credit requirements identified above are intended to conform to the Federal requirements of 30 CFR 800.50 and sections 509 and 519 of SMCRA.

IV. Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are seeking your comments on whether the amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the West Virginia program.

Written Comments

Send your written comments to OSMRE at one of the addresses given above. Your written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of your recommendations. We may not consider or respond to your comments when developing the final rule if they are received after the close of the comment period (see **DATES**) or sent to an address other than those listed above (see **ADDRESSES**).

Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

V. Procedural Determinations

Executive Order 12866—Regulatory Planning and Review

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866.

Other Laws and Executive Orders Affecting Rulemaking

When a State submits a program amendment to OSMRE for review, our regulations at 30 CFR 732.17(h) require us to publish a notice in the **Federal Register** indicating receipt of the proposed amendment, its text or a summary of its terms, and an opportunity for public comment. We conclude our review of the proposed amendment after the close of the public comment period and determine whether the amendment should be approved, approved in part, or not approved. At that time, we will also make the determinations and certifications required by the various laws and executive orders governing the rulemaking process and include them in the final rule.

List of Subjects in 30 CFR Part 948

Intergovernmental relations, Surface mining, Underground mining.

Dated: September 12, 2014.

Thomas D. Shope,

Regional Director, Appalachian Region.

[FR Doc. 2014–26659 Filed 11–12–14; 8:45 am]

BILLING CODE 4310–05-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2014–0610; FRL–9919–08–Region 4]

Approval and Promulgation of Implementation Plans; Region 4 States; 2008 Lead, 2008 Ozone and 2010 Nitrogen Dioxide Prevention of Significant Deterioration Infrastructure Plans

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve portions of submissions from Alabama, Florida, Georgia, Kentucky, Mississippi, South Carolina and Tennessee for inclusion into each State's implementation plan. This proposal pertains to the Clean Air Act (CAA or Act) infrastructure requirements for the 2008 Lead, 2008 Ozone and 2010 Nitrogen Dioxide (NO₂) National Ambient Air Quality Standards (NAAQS). The CAA requires that each state adopt and submit a state implementation plan (SIP) for the implementation, maintenance, and enforcement of each NAAQS promulgated by EPA. These plans are

commonly referred to as “infrastructure” SIPs (hereafter referred to as “infrastructure SIP submissions”). Specifically, EPA is proposing to approve the portions of the submissions from Alabama, Florida, Georgia, Kentucky, Mississippi, South Carolina and Tennessee that relate to the infrastructure SIP prevention of significant deterioration (PSD) requirements. All other applicable infrastructure requirements for the 2008 Lead, 2008 Ozone and 2010 NO₂ NAAQS associated with these States are being addressed in separate rulemakings.

DATES: Written comments must be received on or before December 15, 2014.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2014–0610, by one of the following methods:

1. www.regulations.gov: Follow the on-line instructions for submitting comments.
2. Email: R4-RDS@epa.gov.
3. Fax: (404) 562–9019.
4. Mail: “EPA–R04–OAR–2014–0610,” Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960.
5. Hand Delivery or Courier: Lynorae Benjamin, Chief, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R04–OAR–2014–0610. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through www.regulations.gov or email, information that you consider to be CBI or otherwise protected. The www.regulations.gov Web site is an “anonymous access” system, which means EPA will not know your identity

or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through www.regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

Docket: All documents in the electronic docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Sean Lakeman, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960. The telephone number is (404) 562-9043. Mr. Lakeman can be reached via electronic mail at lakeman.sean@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

By statute, SIPs meeting the requirements of sections 110(a)(1) and

(2) are to be submitted by states within three years after promulgation of a new or revised NAAQS to provide for the implementation, maintenance, and enforcement of the new or revised NAAQS. EPA has historically referred to these SIP submissions made for the purpose of satisfying the requirements of CAA sections 110(a)(1) and 110(a)(2) as "infrastructure SIP" submissions. Sections 110(a)(1) and (2) require states to address basic SIP elements such as for monitoring, basic program requirements and legal authority that are designed to assure attainment and maintenance of the newly established or revised NAAQS. More specifically, section 110(a)(1) provides the procedural and timing requirements for SIPs. Section 110(a)(2) lists specific elements that states must meet for the "infrastructure" SIP requirements related to a newly established or revised NAAQS. The contents of an infrastructure SIP submission may vary depending upon the data and analytical tools available to the state, as well as the provisions already contained in the state's implementation plan at the time in which the state develops and submits the submission for a new or revised NAAQS.

Through this action, EPA is proposing approval of the PSD requirements of sections 110(a)(2)(C), 110(a)(2)(D)(i)(II) (prong 3) and 110(a)(2)(J) (hereafter "PSD Elements") for various infrastructure SIP submissions from the states of Alabama, Florida, Georgia, Kentucky, Mississippi, South Carolina and Tennessee. As described further below, for some of these states, EPA is proposing approval of the PSD Elements in the infrastructure SIP submissions for the 2008 Lead, 2008 Ozone and 2010 NO₂ NAAQS; whereas for other states, EPA is only proposing approval of the PSD Elements of the infrastructure SIP submissions for a subset of these NAAQS. All other applicable infrastructure requirements for the 2008 Lead, 2008 Ozone and 2010 NO₂ NAAQS associated with these States are being addressed in separate rulemakings.

A brief background regarding the NAAQS relevant to today's proposal is provided below. For comprehensive information on these NAAQS, please refer to the **Federal Register** rulemakings cited below.

a. 2008 Lead NAAQS

On October 5, 1978, EPA promulgated a revised NAAQS for Lead under section 109 of the Act. See 43 FR 46246. The Lead standard was set at a level of 1.5 micrograms per cubic meter (µg/m³), measured as Lead in total suspended

particulate matter (Pb-TSP), not to be exceeded by the maximum arithmetic mean concentration averaged over a calendar quarter. This standard was based on the 1977 Air Quality Criteria for Lead. On November 12, 2008 (75 FR 81126), EPA issued a final rule to revise the Lead NAAQS. The Lead NAAQS was revised to 0.15 µg/m³. States were required to submit infrastructure SIP submissions to EPA no later than October 15, 2011, for the 2008 Lead NAAQS.

For the 2008 Lead NAAQS, EPA is only addressing the PSD Elements of the infrastructure SIP submissions from Alabama (received November 4, 2011), Florida (received October 14, 2011), Georgia (received May 14, 2012), Kentucky (received July 17, 2012), Mississippi (received November 17, 2011), and South Carolina's (received September 20, 2011). EPA notes that the Agency approved the PSD Elements of Tennessee's 2008 Lead infrastructure SIP submission on August 12, 2013 (78 FR 48806).

b. 2008 Ozone NAAQS

On March 27, 2008, EPA promulgated a revised NAAQS for ozone based on 8-hour average concentrations. EPA revised the level of the 8-hour Ozone NAAQS to 0.075 parts per million. See 77 FR 16436. States were required to submit infrastructure SIP submissions for the 2008 8-hour Ozone NAAQS to EPA no later than March 2011.

For the 2008 Ozone NAAQS, EPA is only addressing the PSD Elements of the infrastructure SIP submissions from Alabama (received August 20, 2012), Georgia (received March 6, 2012), Mississippi (received May 29, 2012; and resubmitted July 26, 2012), and South Carolina (received on July 17, 2012). EPA notes that the Agency approved the PSD Elements of the Florida, Kentucky and Tennessee infrastructure SIP submissions for the 2008 Ozone NAAQS on May 19, 2014 (79 FR 28607),¹ March 7, 2013 (78 FR 14691), and March 6, 2013 (78 FR 14450), respectively.

c. 2010 NO₂ NAAQS

On February 9, 2010 (75 FR 6474), EPA established a new 1-hour primary NAAQS for NO₂ at a level of 100 parts per billion (ppb), based on a 3-year average of the 98th percentile of the yearly distribution of 1-hour daily maximum concentrations. States were required to submit infrastructure SIP

¹ On May 19, 2014, EPA took final action to approve Florida's December 19, 2013, SIP revision to adopt the Greenhouse Gas (GHG) Tailoring Rule into the Florida SIP. See 79 FR 28607. See Section V below for more detailed information.

submissions for the 2010 NO₂ NAAQS to EPA no later than January 2013.

For the 2010 NO₂ NAAQS, EPA is addressing the PSD Elements of the infrastructure SIP submissions from Alabama (received April 23, 2013), Florida (received January 22, 2013), Georgia (received March 25, 2013), Kentucky (received April 26, 2013), Mississippi (received February 28, 2013), South Carolina (received April 30, 2014), and Tennessee (received March 13, 2014).

II. What is EPA's approach to the review of infrastructure SIP submissions?

EPA is acting upon the PSD Elements portions of SIP submissions that address the infrastructure requirements of CAA sections 110(a)(1) and 110(a)(2) for the 2008 Lead, 2008 Ozone and 2010 NO₂ NAAQS for various states in Region 4. The requirement for states to make a SIP submission of this type arises out of CAA section 110(a)(1). Pursuant to section 110(a)(1), states must make SIP submissions "within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof)," and these SIP submissions are to provide for the "implementation, maintenance, and enforcement" of such NAAQS. The statute directly imposes on states the duty to make these SIP submissions, and the requirement to make the submissions is not conditioned upon EPA's taking any action other than promulgating a new or revised NAAQS. Section 110(a)(2) includes a list of specific elements that "[e]ach such plan" submission must address.

EPA has historically referred to these SIP submissions made for the purpose of satisfying the requirements of CAA sections 110(a)(1) and 110(a)(2) as "infrastructure SIP" submissions. Although the term "infrastructure SIP" does not appear in the CAA, EPA uses the term to distinguish this particular type of SIP submission from submissions that are intended to satisfy other SIP requirements under the CAA, such as "nonattainment SIP" or "attainment plan SIP" submissions to address the nonattainment planning requirements of part D of title I of the CAA, "regional haze SIP" submissions required by EPA rule to address the visibility protection requirements of CAA section 169A, and nonattainment new source review permit program submissions to address the permit requirements of CAA, title I, part D. Section 110(a)(1) addresses the timing and general requirements for infrastructure SIP submissions, and

section 110(a)(2) provides more details concerning the required contents of these submissions.

Historically, EPA has elected to use guidance documents to make recommendations to states for infrastructure SIPs, in some cases conveying needed interpretations on newly arising issues and in some cases conveying interpretations that have already been developed and applied to individual SIP submissions for particular elements.² EPA most recently issued guidance for infrastructure SIPs on September 13, 2013 (2013 Guidance).³ EPA developed this document to provide states with up-to-date guidance for infrastructure SIPs for any new or revised NAAQS. Within this guidance, EPA describes the duty of states to make infrastructure SIP submissions to meet basic structural SIP requirements within three years of promulgation of a new or revised NAAQS. EPA also made recommendations about many specific subsections of section 110(a)(2) that are relevant in the context of infrastructure SIP submissions.⁴ The guidance also discusses the substantively important issues that are germane to certain subsections of section 110(a)(2). Significantly, EPA interprets sections 110(a)(1) and 110(a)(2) such that infrastructure SIP submissions need to address certain issues and need not address others. Accordingly, EPA reviews each infrastructure SIP submission for compliance with the applicable statutory provisions of section 110(a)(2), as appropriate.

² EPA notes, however, that nothing in the CAA requires EPA to provide guidance or to promulgate regulations for infrastructure SIP submissions. The CAA directly applies to states and requires the submission of infrastructure SIP submissions, regardless of whether or not EPA provides guidance or regulations pertaining to such submissions. EPA elects to issue such guidance in order to assist states, as appropriate.

³ "Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2)," Memorandum from Stephen D. Page, September 13, 2013. EPA notes that this 2013 Infrastructure SIP Guidance document was not intended to apply to infrastructure SIP submissions for the 2008 Lead NAAQS.

⁴ EPA's September 13, 2013, guidance did not make recommendations with respect to infrastructure SIP submissions to address section 110(a)(2)(D)(i)(I). EPA issued the guidance shortly after the U.S. Supreme Court agreed to review the D.C. Circuit decision in *EME Homer City*, 696 F.3d 7 (D.C. Cir. 2012) which had interpreted the requirements of section 110(a)(2)(D)(i)(I). In light of the uncertainty created by ongoing litigation, EPA elected not to provide additional guidance on the requirements of section 110(a)(2)(D)(i)(I) at that time. As the guidance is neither binding nor required by statute, whether EPA elects to provide guidance on a particular section has no impact on a state's CAA obligations.

EPA's review of infrastructure SIP submissions with respect to the PSD program requirements in sections 110(a)(2)(C), (D)(i)(II), and (J) focuses upon the structural PSD program requirements contained in part C and EPA's PSD regulations. Structural PSD program requirements include provisions necessary for the PSD program to address all regulated sources and new source review (NSR) pollutants, including greenhouse gases (GHGs). By contrast, structural PSD program requirements do not include provisions that are not required under EPA's regulations at 40 CFR 51.166 but are merely available as an option for the state, such as the option to provide grandfathering of complete permit applications with respect to the 2012 PM_{2.5} NAAQS. Accordingly, the latter optional provisions are types of provisions EPA considers irrelevant in the context of an infrastructure SIP action.

EPA's approach to review of infrastructure SIP submissions is to identify the CAA requirements that are logically applicable to that submission. EPA believes that this approach to the review of a particular infrastructure SIP submission is appropriate, because it would not be reasonable to read the general requirements of section 110(a)(1) and the list of elements in 110(a)(2) as requiring review of each and every provision of a state's existing SIP against all requirements in the CAA and EPA regulations merely for purposes of assuring that the state in question has the basic structural elements for a functioning SIP for a new or revised NAAQS. Because SIPs have grown by accretion over the decades as statutory and regulatory requirements under the CAA have evolved, they may include some outmoded provisions and historical artifacts. These provisions, while not fully up to date, nevertheless may not pose a significant problem for the purposes of "implementation, maintenance, and enforcement" of a new or revised NAAQS when EPA evaluates adequacy of the infrastructure SIP submission. EPA believes that a better approach is for states and EPA to focus attention on those elements of section 110(a)(2) of the CAA most likely to warrant a specific SIP revision due to the promulgation of a new or revised NAAQS or other factors.

EPA believes that its approach with respect to infrastructure SIP requirements is based on a reasonable reading of sections 110(a)(1) and 110(a)(2) because the CAA provides other avenues and mechanisms to address specific substantive deficiencies in existing SIPs. These other statutory

tools allow EPA to take appropriately tailored action, depending upon the nature and severity of the alleged SIP deficiency. Section 110(k)(5) authorizes EPA to issue a “SIP call” whenever the Agency determines that a state’s implementation plan is substantially inadequate to attain or maintain the NAAQS, to mitigate interstate transport, or to otherwise comply with the CAA.⁵ Section 110(k)(6) authorizes EPA to correct errors in past actions, such as past approvals of SIP submissions.⁶ Significantly, EPA’s determination that an action on a state’s infrastructure SIP submission is not the appropriate time and place to address all potential existing SIP deficiencies does not preclude EPA’s subsequent reliance on provisions in section 110(a)(2) as part of the basis for action to correct those deficiencies at a later time. For example, although it may not be appropriate to require a state to eliminate all existing inappropriate director’s discretion provisions in the course of acting on an infrastructure SIP submission, EPA believes that section 110(a)(2)(A) may be among the statutory bases that EPA relies upon in the course of addressing such deficiency in a subsequent action.⁷

III. What are states required to address under Sections 110(a)(2)(C), 110(a)(2)(D)(i)(II) (Prong 3) and 110(a)(2)(f) related to PSD?

Section 110(a)(2)(C) has three components that must be addressed in infrastructure SIP submissions: Enforcement, state-wide regulation of new and modified minor sources and minor modifications of major sources; and PSD permitting of major sources

⁵ For example, EPA issued a SIP call to Utah to address specific existing SIP deficiencies related to the treatment of excess emissions during SSM events. See “Finding of Substantial Inadequacy of Implementation Plan; Call for Utah State Implementation Plan Revisions,” 74 FR 21639 (April 18, 2011).

⁶ EPA has used this authority to correct errors in past actions on SIP submissions related to PSD programs. See “Limitation of Approval of Prevention of Significant Deterioration Provisions Concerning Greenhouse Gas Emitting-Sources in State Implementation Plans; Final Rule,” 75 FR 82536 (December 30, 2010). EPA has previously used its authority under CAA section 110(k)(6) to remove numerous other SIP provisions that the Agency determined it had approved in error. See, e.g., 61 FR 38664 (July 25, 1996) and 62 FR 34641 (June 27, 1997) (corrections to American Samoa, Arizona, California, Hawaii, and Nevada SIPs); 69 FR 67062 (November 16, 2004) (corrections to California SIP); and 74 FR 57051 (November 3, 2009) (corrections to Arizona and Nevada SIPs).

⁷ See, e.g., EPA’s disapproval of a SIP submission from Colorado on the grounds that it would have included a director’s discretion provision inconsistent with CAA requirements, including section 110(a)(2)(A). See, e.g., 75 FR 42342 at 42344 (July 21, 2010) (proposed disapproval of director’s discretion provisions); 76 FR 4540 (Jan. 26, 2011) (final disapproval of such provisions).

and major modifications in areas designated attainment or unclassifiable for the subject NAAQS as required by CAA title I part C (i.e., the major source PSD program).

Section 110(a)(2)(D)(i) has two components; 110(a)(2)(D)(i)(I) and 110(a)(2)(D)(i)(II). Each of these components have two subparts resulting in four distinct components, commonly referred to as “prongs,” that must be addressed in infrastructure SIP submissions. The first two prongs, which are codified in section 110(a)(2)(D)(i)(I), are provisions that prohibit any source or other type of emissions activity in one state from contributing significantly to nonattainment of the NAAQS in another state (“prong 1”), and interfering with maintenance of the NAAQS in another state (“prong 2”). The third and fourth prongs, which are codified in section 110(a)(2)(D)(i)(II), are provisions that prohibit emissions activity in one state interfering with measures required to prevent significant deterioration of air quality in another state (“prong 3”), or to protect visibility in another state (“prong 4”).

Section 110(a)(2)(f) has four components that must be addressed in infrastructure SIP submissions: (1) consultation with government officials, (2) public notification, (3) prevention of significant deterioration, and (4) visibility protection.

With respect to the PSD Elements of these sections, EPA interprets the CAA to require each state to make, for each new or revised NAAQS, an infrastructure SIP submission that demonstrates that the air agency has a complete PSD permitting program meeting the current requirements for all regulated NSR pollutants. The requirements of the PSD Elements may also be satisfied by demonstrating that the air agency has a complete PSD permitting program correctly addressing all regulated NSR pollutants.

IV. What are the PSD program requirements?

In addition to analyzing whether a state has adequate authority to regulate new and modified sources to assist in the protection of air quality, there are also four structural PSD program requirements that are relevant to EPA’s review of the PSD Elements of the infrastructure SIP submissions for the 2008 Lead, 2008 Ozone and 2010 NO₂ NAAQS. The EPA regulations that require these SIP revisions are: (1) The Phase II Rule⁸; (2) the Greenhouse Gas

(GHG) Tailoring Rule⁹ as consistent with the holding in *Utility Air Regulatory Group v. Environmental Protection Agency*; ¹⁰ (3) the NSR Fine Particulate Matter (PM_{2.5}) Rule¹¹; and, (4) the PM_{2.5} PSD Increment-Significant Impact Levels (SILs)-Significant Monitoring Concentrations (SMC) Rule (only as it relates to PM_{2.5} Increments).¹² Specific details on these PSD requirements can be found in the respective final rules cited above, however, a brief summary of each rule is provided below.

The Phase II rule established federal NSR permitting requirements for the implementation of the ozone NAAQS including recognizing nitrogen oxide as an ozone precursor. See 70 FR 71612.

The GHG Tailoring Rule established emission thresholds for determining which new stationary sources and modification projects become subject to PSD permitting requirements for their GHG emissions. See 75 FR 31514. EPA notes, that on June 23, 2014, the United States Supreme Court issued a decision addressing the application of PSD permitting requirements to GHG emissions. See *Utility Air Regulatory Group v. Environmental Protection Agency*, 134 S. Ct. 2427. In that decision, the Supreme Court held that the EPA may not treat GHGs as an air pollutant for purposes of determining whether a source is a major source required to obtain a PSD permit. The Court also determined that the EPA could continue to require that PSD permits, otherwise required based on emissions of pollutants other than GHGs, contain limitations on GHG emissions based on the application of Best Available Control Technology (BACT). In order to act consistently with its understanding of the Court’s decision pending further judicial action to effectuate the decision, the EPA is not continuing to apply EPA regulations that would require that SIPs include

Final Rule” (November 29, 2005, 70 FR 71612) (hereafter referred to as the “Phase II Rule”).

⁹ Prevention of Significant Deterioration and Title V Greenhouse Gas (GHG) Tailoring Rule; Final Rule” (June 3, 2010, 75 FR 31514) (hereafter referred to as the “GHG Tailoring Rule”).

¹⁰ *Utility Air Regulatory Group v. Environmental Protection Agency*, 134 S. Ct. 2427 (2014).

¹¹ Implementation of the New Source Review Program for Particulate Matter Less Than 2.5 Micrometers; Final Rule” (May 16, 2008, 73 FR 28321) (hereafter referred to as the “NSR PM_{2.5} Rule”).

¹² “Final Rule on the Prevention of Significant Deterioration (PSD) for Particulate Matter Less Than 2.5 Micrometers (PM_{2.5})—Increments, Significant Impact Levels (SILs) and Significant Monitoring Concentration (SMC); Final Rule” (October 20, 2010, 75 FR 64864) (hereafter referred to as the “PM_{2.5} PSD Increment-SILs-SMC Rule (only as it relates to PM_{2.5} Increments)”).

⁸ “Final Rule To Implement the 8-Hour Ozone National Ambient Air Quality Standard—Phase 2;

permitting requirements that the Supreme Court found impermissible. Specifically, EPA is not applying the requirement that a state's SIP-approved PSD program require that sources obtain PSD permits when GHGs are the only pollutant (i) that the source emits or has the potential to emit above the major source thresholds, or (ii) for which there is a significant emissions increase and a significant net emissions increase from a modification (e.g. 40 CFR 51.166(b)(48)(v)). EPA anticipates a need to revise federal PSD rules in light of the Supreme Court opinion. In addition, EPA anticipates that many states will revise their existing SIP-approved PSD programs in light of the Supreme Court's decision. The timing and content of subsequent EPA actions with respect to the EPA regulations and state PSD program approvals are expected to be informed by additional legal process before the United States District Court for the District of Columbia Circuit. At this juncture, EPA is not expecting states to have revised their PSD programs for purposes of infrastructure SIP submissions and is only evaluating such submissions to assure that the state's program correctly addresses GHGs consistent with the Supreme Court's decision.

The 2008 NSR PM_{2.5} Rule¹³ and 2010 PM_{2.5} PSD Increment-SILs-SMC Rule

¹³ On January 4, 2013, the U.S. Court of Appeals, in *Natural Resources Defense Council v. EPA*, No. 08–1250, 2013 WL 45653 (D.C. Cir., filed July 15, 2008) (consolidated with 09–1102, 11–1430), issued a judgment that remanded EPA's 2007 and 2008 rules implementing the PM_{2.5} NAAQS. The court concluded that since subpart 4 of the CAA generally applies to PM₁₀, EPA should have also followed the more prescriptive subpart 4 structure for the PM_{2.5} implementation rules. The court ordered EPA to repromulgate the implementation rules pursuant to subpart 4. Subpart 4 of Part D, Title 1 of the CAA establishes additional provisions for particulate matter nonattainment areas.

The 2008 implementation rule addressed by the court decision, "Implementation of New Source Review (NSR) Program for Particulate Matter Less Than 2.5 Micrometers (PM_{2.5})," 73 FR 28321 (May 16, 2008), promulgated NSR requirements for implementation of PM_{2.5} in both nonattainment areas (nonattainment NSR) and attainment/unclassifiable areas (PSD). As the requirements of Subpart 4 only pertain to nonattainment areas, EPA does not consider the portions of the 2008 rule that address requirements for PM_{2.5} attainment and unclassifiable areas to be affected by the court's opinion. Moreover, EPA does not anticipate the need to revise any PSD requirements promulgated in the 2008 rule in order to comply with the court's decision. Accordingly, EPA's approval of state's infrastructure SIP related to elements (C), (D)(i) (prong 3), or (J) with respect to the PSD requirements promulgated in the 2008 NSR PM_{2.5} Rule does not conflict with the court's opinion.

The court's decision with respect to the nonattainment NSR requirements promulgated by the 2008 implementation rule also does not affect EPA's action on the present infrastructure actions. EPA interprets the Act to exclude nonattainment area requirements, including requirements

(only as it relates to PM_{2.5} Increments) established NSR permitting requirements for the implementation of the PM_{2.5} NAAQS including increments pursuant to section 166(a) of the CAA to prevent significant deterioration of air quality in areas meeting the NAAQS. See 73 FR 28321 and 75 FR 64864. On January 22, 2013, the U.S. Court of Appeals for the District of Columbia, in *Sierra Club v. EPA*, 703 F.3d 458 (D.C. Cir. 2013), issued a judgment that, among other things, vacated the provisions adding the PM_{2.5} SMC to the Federal regulations, at 40 CFR 51.166(i)(5)(i)(c) and 52.21(i)(5)(i)(c), that were promulgated as part of the 2010 PM_{2.5} PSD Increment-SILs-SMC Rule.¹⁴ See 75 FR 64864; see also, *Sierra Club v. EPA*, 703 F.3d 458 (D.C. Cir. 2013). In its decision, the court held that EPA did not have the authority to use SMCs to exempt permit applicants from the statutory requirement in section 165(e)(2) of the CAA that ambient monitoring data for PM_{2.5} be included in all PSD permit applications. Thus, although the PM_{2.5} SMC was not a required element of a State's PSD program and thus not a structural requirement for purposes of infrastructure SIPs, were a SIP-approved PSD program that contains such a provision to use that provision to issue new permits without requiring ambient PM_{2.5} monitoring data, such application of the SIP would be inconsistent with the court's opinion and the requirements of section 165(e)(2) of the CAA. Of the States that are the subject of today's proposed rulemaking, EPA approved the SMC's into the Alabama, Florida and Mississippi SIP on September 26, 2012 (77 FR 59100), September 19, 2012 (77 FR 58027), and September 26, 2012 (77 FR 59095), respectively. However, given the clarity of the court's decision, it would now be inappropriate for these states to continue to allow applicants for any pending or future PSD permits to rely on the PM_{2.5} SMC in order to avoid compiling ambient monitoring data for PM_{2.5}. Because of the vacatur of the EPA regulations, the SMC provisions,

associated with a nonattainment NSR program, from infrastructure SIP submissions due 3 years after adoption or revision of a NAAQS. Instead, these elements are typically referred to as nonattainment SIP or attainment plan elements, which would be due by the dates statutorily prescribed under subpart 2 through 5 under part D, extending as far as 10 years following designations for some elements.

¹⁴ "Prevention of Significant Deterioration (PSD) for Particulate Matter Less Than 2.5 Micrometers (PM_{2.5})—Increments, Significant Impact Levels (SILs) and Significant Monitoring Concentration (SMC); Final Rule, 75 FR 64864 (October 20, 2010)."

included in these States' SIP-approved PSD programs on the basis of EPA's regulations are unlawful and no longer enforceable by law. Permits issued on the basis of these provisions as they appear in approved SIPs would be inconsistent with the CAA and difficult to defend in administrative and judicial challenges. Thus, the SIP provisions may not be applied even prior to their removal from the SIPs. Alabama, Florida and Mississippi should instead require applicants requesting a PSD permit, including those having already been applied for but for which the permit has not yet been received, to submit ambient PM_{2.5} monitoring data in accordance with the CAA requirements whenever either direct PM_{2.5} or any PM_{2.5} precursor is emitted in a significant amount.¹⁵

On December 9, 2013, EPA issued a final rulemaking to remove the vacated and remanded PM_{2.5} SILs¹⁶ and the vacated PM_{2.5} SMC provisions from 40 CFR 51.166 and 52.21.¹⁷ See 79 FR 73698. Because the Court vacated the PM_{2.5} SMC provisions in 40 CFR 51.166(i)(5)(i)(c) and 52.21(i)(5)(i)(c), EPA revised the existing concentration for the PM_{2.5} SMC listed in sections 51.166(i)(5)(i)(c) and 52.21(i)(5)(i)(c) to zero micrograms per cubic meter (0 mg/m³). Were EPA to completely remove PM_{2.5} from the list of pollutants in sections 51.166(i)(5)(i)(c) and 52.21(i)(5)(i)(c) of the PSD regulations, PM_{2.5} would no longer be a listed pollutant.

EPA did not entirely remove PM_{2.5} as a listed pollutant in the SMC provisions so as to avoid any potential that sections 51.166(i)(5)(iii) and 52.21(i)(5)(iii) could be interpreted as giving reviewing authorities the discretion to exempt permit applicants from the requirement to conduct monitoring for PM_{2.5}. Such a

¹⁵ In lieu of the applicants' need to set out PM_{2.5} monitors to collect ambient data, applicants may submit PM_{2.5} ambient data collected from existing monitoring networks when the permitting authority deems such data to be representative of the air quality in the area of concern for the year preceding receipt of the application. EPA believes that applicants will generally be able to rely on existing representative monitoring data to satisfy the monitoring data requirement.

¹⁶ The court's January 22, 2013, decision also vacated and remanded back to EPA the PM_{2.5} SILs. EPA's December 9, 2013 final rule also removed the PM_{2.5} SILs from the CFR. The PM_{2.5} SILs are not a required element of a State's PSD program and thus not a structural requirement for purposes of infrastructure SIPs. The PM_{2.5} SILs are not approved into the SIPs that are the subject of this proposed rulemaking.

¹⁷ Final Rule entitled "Prevention of Significant Deterioration for Particulate Matter Less Than 2.5 Micrometers—Significant Impact Levels and Significant Monitoring Concentration: Removal of Vacated Elements;" 79 FR 73698 (December 9, 2013).

conclusion would contravene the Court's decision and the CAA.

By continuing to include PM_{2.5} as a pollutant in the list contained in sections 51.166(i)(5)(i) and 52.21(i)(5)(i), with the numerical value replaced with 0 mg/m³, we avoid any concern that paragraph (iii) of the two affected sections could be applied to excuse permit applicants from adequately addressing the monitoring requirement for PM_{2.5}.

EPA also advises states to begin preparations to remove the PM_{2.5} provisions from their state PSD regulations and SIPs. As the previously-approved PM_{2.5} SMC provisions in the Alabama, Florida and Mississippi SIP are no longer enforceable, EPA does not

believe the existence of these provisions in the States' implementation plans precludes today's proposed rulemaking to approve the infrastructure SIP submissions for Alabama, Florida and Mississippi as the submissions relate to the PSD elements of the 2008 Lead, 2008 Ozone and 2010 NO₂ NAAQS.

V. What is EPA's analysis of how Region 4 states addressed sections 110(a)(2)(C), 110(a)(2)(D)(i)(II) (prong 3) and 110(a)(2)(J) related to PSD?

Described below is EPA's analysis of how the Alabama, Florida, Georgia, Kentucky, Mississippi, South Carolina and Tennessee infrastructure SIP submissions meet the requirements of the PSD Elements for the NAAQS for

which they were submitted. This analysis includes review of the EPA's previous approval of the four structural PSD program requirements with respect to each of the states addressed in this action. Table 1 below summarizes EPA approvals of these structural PSD program requirements into the Alabama, Florida, Georgia, Kentucky, Mississippi, South Carolina and Tennessee SIPs. EPA's rationale for today's proposal with respect to each State is provided below. All other applicable infrastructure requirements for the 2008 Lead, 2008 Ozone and 2010 NO₂ NAAQS associated with these States are being addressed in separate rulemakings.

TABLE 1—EPA APPROVED STRUCTURAL PSD PROGRAM REQUIREMENTS

State	Phase II rule	Greenhouse gas (GHG) tailoring rule	NSR PM _{2.5} rule	PM _{2.5} PSD increment-SILs-SMC rule
Alabama	May 1, 2008 (73 FR 23957)	December 29, 2010 (75 FR 81863).	September 26, 2012 (77 FR 59100).	September 26, 2012 (77 FR 59100).
Florida	June 15, 2012 (77 FR 35862)	May 19, 2014 (79 FR 28607)	September 19, 2012 (77 FR 58027).	September 19, 2012 (77 FR 58027).
Georgia	November 22, 2010 (75 FR 71018).	September 8, 2011 (76 FR 55572).	September 8, 2011 (76 FR 55572).	April 9, 2013 (78 FR 21065).
Kentucky	September 15, 2010 (75 FR 55988).	December 29, 2010 (75 FR 81868).	Refer to Footnote ¹⁸	Refer to Footnote. ¹⁸
Mississippi	December 20, 2010 (75 FR 79300).	December 29, 2010 (75 FR 81858).	September 26, 2012 (77 FR 59095).	September 26, 2012 (77 FR 59095).
South Carolina ..	June 23, 2011 (77 FR 36875)	Refer to Footnote ¹⁹	June 23, 2011 (77 FR 36875)	April 3, 2013 (78 FR 19994).
Tennessee	February 7, 2012 (77 FR 6016).	February 28, 2012 (77 FR 11744).	July 30, 2012 (77 FR 44481)	January 9, 2014 (79 FR 1593).

¹⁸ Through a final rule signed by the EPA Region 4 Administrator, on October 22, 2014, EPA is took final action in a separate rulemaking to approve Kentucky's January 13, 2013, SIP revision which addresses the NSR PM_{2.5} Rule and the PM_{2.5} PSD Increment-SILs-SMC Rule requirements. EPA proposed approval of Kentucky's January 13, 2013, SIP revision on July 23, 2014 (79 FR 42745).

¹⁹ On June 11, 2010, the South Carolina Governor signed an Executive Order to confirm that the State had authority to implement appropriate emission thresholds for determining which new stationary sources and modification projects become subject to PSD permitting requirements for their GHG emissions at the state level. On December 30, 2010, EPA published a final rulemaking, "Action To Ensure Authority To Implement Title V Permitting Programs Under the Greenhouse Gas Tailoring Rule" (75 FR 82254) to narrow EPA's previous approval of State title V operating permit programs that apply (or may apply) to GHG-emitting sources; this rule hereafter is referred to as the "Narrowing Rule." EPA narrowed its previous approval of certain State permitting thresholds, for GHG emissions so that only sources that equal or exceed the GHG thresholds, as established in the final Tailoring Rule, would be covered as major sources by the Federally-approved programs in the affected States. South Carolina was included in this rulemaking. On March 4, 2011, South Carolina submitted a letter withdrawing from EPA's consideration the portion of South Carolina's SIP for which EPA withdrew its previous approval in the Narrowing Rule. These provisions are no longer intended for inclusion in the SIP, and are no longer

a. Alabama

For the 2008 Lead, 2008 Ozone and 2010 NO₂ NAAQS, Alabama's authority to regulate new and modified sources to assist in the protection of air quality in Alabama is established in the Alabama Administrative Code Chapters 335–3–14–.01 "General Provisions," 335–3–14–.02 "Permit Procedure," 334–3–14–.03 "Standards for Granting Permits," 335–3–14–.04 "Prevention of Significant Deterioration in Permitting," and 335–3–14–.05 "Air Permits Authorizing Construction in or Near Nonattainment Areas." Alabama's infrastructure SIP submissions demonstrate that new major sources and major modifications in areas of the state designated attainment or unclassifiable for the specified NAAQS are subject to a federally-approved PSD permitting program meeting all the current structural requirements of part C of title I of the CAA to satisfy the infrastructure SIP PSD Elements, including the

before EPA for its approval or disapproval. A copy of South Carolina's letter can be accessed at www.regulations.gov using Docket ID No. EPA–R04–OAR–2014–0610.

authority to regulate GHG emitting sources consistent with the holding in *Utility Air Regulatory Group v. Environmental Protection Agency*, for purposes of the 2008 Lead, 2008 Ozone and 2010 NO₂ NAAQS (See Table 1).

As such, EPA has made the preliminary determination that Alabama's SIP and practices are adequate and comply with PSD Elements of the 2008 Lead, 2008 Ozone and 2010 NO₂ NAAQS. Accordingly, in this action EPA is proposing to approve Alabama's infrastructure SIP submissions as satisfying the infrastructure SIP PSD Elements for the 2008 Lead, 2008 Ozone and 2010 NO₂ NAAQS.

b. Florida

For the 2008 Lead and 2010 NO₂ NAAQS, Florida's authority to regulate new and modified sources to assist in the protection of air quality in nonattainment, attainment or unclassifiable areas is established in Florida Administrative Code Chapters 62–210, *Stationary Sources—General Requirements, Section 200—Definitions*; and 62–212, and *Stationary Sources—*

Preconstruction Review, Section 400—Prevention of Significant Deterioration, of the Florida SIP. Florida's infrastructure SIP submissions demonstrate that new major sources and major modifications in areas of the state designated attainment or unclassifiable for the specified NAAQS are subject to a federally-approved PSD permitting program meeting all the current structural requirements of part C of title I of the CAA to satisfy the infrastructure SIP PSD Elements, including the authority to regulate GHG emitting sources consistent with the holding in *Utility Air Regulatory Group v. Environmental Protection Agency*, for purposes of the 2008 Lead and 2010 NO₂ NAAQS (See Table 1).

As such, EPA has made the preliminary determination that Florida's SIP and practices are adequate and comply with PSD Elements of the 2008 Lead and 2010 NO₂ NAAQS. Accordingly, in this action EPA is proposing to approve, Florida's infrastructure SIP submissions as satisfying the infrastructure SIP PSD Elements for the 2008 Lead and the 2010 NO₂ NAAQS.

c. Georgia

For the 2008 Lead, 2008 Ozone and 2010 NO₂ NAAQS, Georgia's authority to regulate new and modified sources to assist in the protection of air quality in Georgia is established in Georgia Regulation 391–3–1–.02(7), *Prevention of Significant Deterioration of Air Quality*, which pertains to the construction or modification of any major stationary source in areas designated as attainment or unclassifiable.

Georgia's infrastructure SIP submissions demonstrate that new major sources and major modifications in areas of the state designated attainment or unclassifiable for the specified NAAQS are subject to a federally-approved PSD permitting program meeting all the current structural requirements of part C of title I of the CAA to satisfy the infrastructure SIP PSD Elements, including the authority to regulate GHG emitting sources consistent with the holding in *Utility Air Regulatory Group v. Environmental Protection Agency*, for purposes of the 2008 Lead, 2008 Ozone and 2010 NO₂ NAAQS (See Table 1).

As such, EPA has made the preliminary determination that Georgia's SIP and practices are adequate and comply with the PSD Elements of the 2008 Lead, 2008 Ozone, and 2010 NO₂ NAAQS. Accordingly, in this action EPA is proposing to approve, Georgia's infrastructure SIP submissions

as satisfying the infrastructure SIP PSD Elements for the 2008 Lead, 2008 Ozone and 2010 NO₂ NAAQS.

d. Kentucky

For the 2008 Lead and 2010 NO₂ NAAQS, Kentucky's authority to regulate new and modified sources to assist in the protection of air quality in nonattainment, attainment or unclassifiable areas is established in Kentucky Administrative Regulation Chapter 51—*Attainment and Maintenance of the National Ambient Air Quality Standards*, which describes the permit requirements for new major sources or major modifications of existing sources in areas classified as attainment or unclassifiable under section 107(d)(1)(A)(ii) or (iii) of the CAA. These requirements are designed to ensure that sources in areas attaining the NAAQS at the time of designations prevent any significant deterioration in air quality. Chapter 51 also establishes the permitting requirements for areas in or around nonattainment areas and provides the Commonwealth's statutory authority to enforce regulations relating to attainment and maintenance of the NAAQS.

Kentucky's infrastructure SIP submissions demonstrate that new major sources and major modifications in areas of the state designated attainment or unclassifiable for the specified NAAQS are subject to a federally-approved PSD permitting program meeting all the current structural requirements of part C of title I of the CAA to satisfy the infrastructure SIP PSD Elements, including the authority to regulate GHG emitting sources consistent with the holding in *Utility Air Regulatory Group v. Environmental Protection Agency*, for purposes of the 2008 Lead and 2010 NO₂ NAAQS (See Table 1).

As such, EPA has made the preliminary determination that Kentucky's SIP and practices are adequate and comply with the PSD Elements of the 2008 Lead and 2010 NO₂ NAAQS. Accordingly, in this action EPA is proposing to approve Kentucky's infrastructure SIP submissions as satisfying the infrastructure SIP PSD Elements for the 2008 Lead and 2010 NO₂ NAAQS.

e. Mississippi

For the 2008 Lead, 2008 Ozone and 2010 NO₂ NAAQS, Mississippi's authority to regulate new and modified sources to assist in the protection of air quality in Mississippi is established in Regulations APC–S–5—*Mississippi Regulations for the Prevention of Significant Deterioration of Air Quality*

and APC–S–2—*Permit Regulation for the Construction and/or Operation of Air Emissions Equipment*. These SIP-approved regulations pertain to the construction of any new major stationary source or any project at an existing major stationary source in an area designated as nonattainment, attainment or unclassifiable. Mississippi's infrastructure SIP submissions demonstrate that new major sources and major modifications in areas of the state designated attainment or unclassifiable for the specified NAAQS are subject to a federally-approved PSD permitting program meeting all the current structural requirements of part C of title I of the CAA to satisfy the infrastructure SIP PSD Elements, including the authority to regulate GHG emitting sources consistent with the holding in *Utility Air Regulatory Group v. Environmental Protection Agency*, for purposes of the 2008 Lead, 2008 Ozone and 2010 NO₂ NAAQS (See Table 1). As such, EPA has made the preliminary determination that Mississippi's SIP and practices are adequate and comply with the PSD Elements requirements of the 2008 Lead, 2008 Ozone, and 2010 NO₂ NAAQS. Accordingly, in this action, EPA is proposing to approve Mississippi's infrastructure SIP submissions as satisfying the infrastructure SIP PSD Elements requirements for the 2008 Lead, 2008 Ozone and 2010 NO₂ NAAQS.

f. South Carolina

For the 2008 Lead, 2008 Ozone and 2010 NO₂ NAAQS, South Carolina's authority to regulate new and modified sources to assist in the protection of air quality in South Carolina is established in Regulations 61–62.1, Section II, *Permit Requirements*; 61–62.5, Standard No. 7, *Prevention of Significant Deterioration*; and 61–62.5, Standard No. 7.1, *Nonattainment New Source Review* of South Carolina's SIP. These regulations pertain to the construction of any new major stationary source or any modification at an existing major stationary source in an area designated as nonattainment, attainment or unclassifiable. South Carolina's infrastructure SIP submissions demonstrate that new major sources and major modifications in areas of the state designated attainment or unclassifiable for the specified NAAQS are subject to a federally-approved PSD permitting program meeting all the current structural requirements of part C of title I of the CAA to satisfy the infrastructure SIP PSD Elements, including the authority to regulate GHG emitting sources consistent with the holding in

Utility Air Regulatory Group v. Environmental Protection Agency, for purposes of the 2008 Lead, 2008 Ozone and 2010 NO₂ NAAQS (See Table 1).

As such, EPA has made the preliminary determination that South Carolina's SIP and practices are adequate and comply with the PSD Elements requirements of the 2008 Lead, 2008 Ozone, and 2010 NO₂ NAAQS. Accordingly, in this action EPA is proposing to approve South Carolina's infrastructure SIP submission as satisfying the infrastructure SIP PSD Elements for the 2008 Lead, 2008 Ozone and 2010 NO₂ NAAQS.

g. Tennessee

For the 2010 NO₂ NAAQS, Tennessee's authority to regulate new and modified sources to assist in the protection of air quality in Tennessee is established in Chapter 1200–3–9, *Construction and Operating Permits*, of the Tennessee SIP. This Chapter pertains to the construction of any new major stationary source or any project at an existing major stationary source in an area designated as nonattainment, attainment or unclassifiable. Tennessee's infrastructure SIP submission demonstrates that new major sources and major modifications in areas of the state designated attainment or unclassifiable for the NO₂ NAAQS are subject to a federally-approved PSD permitting program meeting all the current structural requirements of part C of title I of the CAA to satisfy the infrastructure SIP PSD Elements, including the authority to regulate GHG emitting sources consistent with the holding in *Utility Air Regulatory Group v. Environmental Protection Agency*, for purposes of the 2010 NO₂ NAAQS (See Table 1).

As such, EPA has made the preliminary determination that Tennessee's SIP and practices are adequate and comply with the PSD Elements requirements of the 2010 NO₂ NAAQS. Accordingly, in this action EPA is proposing to approve Tennessee's infrastructure SIP submission as satisfying the infrastructure SIP PSD Elements requirements for the 2010 NO₂ NAAQS.

VI. Proposed Action

As described above, EPA is proposing to approve the portions of the above-described infrastructure SIP submissions from Alabama, Florida, Georgia, Kentucky, Mississippi, South Carolina and Tennessee to address the PSD permitting requirements of sections 110(a)(2)(C), 110(a)(2)(D)(i)(II) (prong 3) and 110(a)(2)(J) of the CAA. As described above, for some of these

states, EPA is proposing approval of the PSD Elements of the infrastructure SIP submissions for the 2008 Lead, 2008 Ozone and 2010 Nitrogen NO₂ NAAQS; whereas for other states, EPA is only proposing approval of the PSD Elements of the infrastructure SIP submissions for a subset of these NAAQS. EPA is proposing approval of these portions of these submissions because they are consistent with section 110 of the CAA.

EPA also notes that, at present, the Agency has preliminarily determined that the Alabama, Florida, Georgia, Kentucky, Mississippi, South Carolina and Tennessee SIPs are sufficient to satisfy the PSD permitting requirements portion of section 110(a)(2)(C), 110(a)(2)(D)(i)(II), prong 3 and 110(a)(2)(J) with respect to GHGs because the PSD permitting program previously-approved by EPA into the SIP continues to require that PSD permits (otherwise required based on emissions of pollutants other than GHGs) contain limitations on GHG emissions based on the application of BACT. Although the approved Alabama, Florida, Georgia, Kentucky, Mississippi, South Carolina and Tennessee PSD permitting programs may currently contain provisions that are no longer necessary in light of the Supreme Court's *Utility Air Regulatory Group v. Environmental Protection Agency* decision, these previous approvals do not render the infrastructure SIP submission inadequate to satisfy sections 110(a)(2)(C), 110(a)(2)(D)(i)(II) (prong 3) and 110(a)(2)(J). The SIPs contain the necessary PSD requirements at this time, and the application of those requirements is not impeded by the presence of other previously-approved provisions regarding the permitting of sources of GHGs that EPA does not consider necessary at this time in light of the Supreme Court decision. Accordingly, the Supreme Court decision does not affect EPA's proposed approval of Alabama, Florida, Georgia, Kentucky, Mississippi, South Carolina and Tennessee's infrastructure SIPs as to the PSD permitting requirements of sections 110(a)(2)(C), 110(a)(2)(D)(i)(II) (prong 3) and 110(a)(2)(J).

VII. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. See 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this proposed action merely approves state law as

meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

With the exception of South Carolina, the SIPs involved in this proposal are not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law." With respect to today's proposed action as it relates to South Carolina, EPA notes that the Catawba Indian Nation Reservation is located within South Carolina and pursuant to the Catawba Indian Claims Settlement Act, S.C. Code Ann. 27–16–120, "all state and local environmental laws and regulations apply to the Catawba Indian Nation and Reservation

and are fully enforceable by all relevant state and local agencies and authorities.” Thus, the South Carolina SIP applies to the Catawba Reservation, however, because today’s proposed action is not approving any specific rule into the South Carolina SIP, but rather proposing that the State’s already approved SIP meets certain CAA requirements, EPA has preliminarily determined that there are no substantial direct effects on the Catawba Indian Nation. EPA has also preliminarily determined that these revisions will not impose any substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Particulate Matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: October 30, 2014.

Anne Heard,

Acting Regional Administrator, Region 4.

[FR Doc. 2014-26737 Filed 11-12-14; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[EPA-HQ-OAR-2013-0602; FRL-9919-07-OAR]

RIN 2060-AR33

Carbon Pollution Emission Guidelines for Existing Stationary Sources: Electric Utility Generating Units

AGENCY: Environmental Protection Agency.

ACTION: Notice; additional information regarding the translation of emission rate-based CO₂ goals to mass-based equivalents.

SUMMARY: The Environmental Protection Agency (EPA) is issuing this notice in support of the proposed rule, “Carbon Pollution Emission Guidelines for Existing Stationary Sources: Electric Utility Generating Units,” published on June 18, 2014 and the supplemental proposal, “Carbon Pollution Emission Guidelines: Existing Stationary Sources in Indian Country and U.S. Territories; Multi-jurisdictional Partnerships,” issued on October 28, 2014, to provide further discussion of potential approaches for translating the emission rate-based carbon dioxide (CO₂) goals

that the EPA has proposed for each affected jurisdiction to an equivalent mass-based metric.

DATES: Comments on the proposed rule published on June 18, 2014, along with the additional information presented in this notice, must be received on or before December 1, 2014.

ADDRESSES: *Comments.* Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2013-0602, by one of the following methods:

Federal eRulemaking portal: <http://www.regulations.gov>. Follow the online instructions for submitting comments.

Email: A-and-R-Docket@epa.gov. Include Docket ID No. EPA-HQ-OAR-2013-0602 in the subject line of the message.

Facsimile: (202) 566-9744. Include Docket ID No. EPA-HQ-OAR-2013-0602 on the cover page.

Mail: Environmental Protection Agency, EPA Docket Center (EPA/DC), Mail code 28221T, Attn: Docket ID No. EPA-HQ-OAR-2013-0602, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

Hand/Courier Delivery: EPA Docket Center, Room 3334, EPA WJC West Building, 1301 Constitution Ave. NW., Washington, DC 20004, Attn: Docket ID No. EPA-HQ-OAR-2013-0602. Such deliveries are accepted only during the Docket Center’s normal hours of operation (8:30 a.m. to 4:30 p.m., Monday through Friday, excluding federal holidays), and special arrangements should be made for deliveries of boxed information.

Instructions: All submissions must include the agency name and Docket ID No. (EPA-HQ-OAR-2013-0602). The EPA’s policy is to include all comments received without change, including any personal information provided, in the public docket, available online at <http://www.regulations.gov>, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or email. Send or deliver information identified as CBI only to the following address: Mr. Roberto Morales, OAQPS Document Control Officer (C404-02), Office of Air Quality Planning and Standards, U.S. EPA, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA-HQ-OAR-2013-0602. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on a disk or CD-ROM that you mail to the EPA, mark the outside

of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information you claim as CBI. In addition to one complete version of the comment that includes information claimed as CBI, you must submit a copy of the comment that does not contain the information claimed as CBI for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

The EPA requests that you also submit a separate copy of your comments to the contact person identified below (see **FOR FURTHER INFORMATION CONTACT**). If the comment includes information you consider to be CBI or otherwise protected, you should send a copy of the comment that does not contain the information claimed as CBI or otherwise protected.

The <http://www.regulations.gov> Web site is an “anonymous access” system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through <http://www.regulations.gov>, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption and be free of any defects or viruses.

Docket: All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available (e.g., CBI or other information whose disclosure is restricted by statute). Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the EPA Docket Center, EPA WJC West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding federal holidays. The telephone number for the Public

Reading Room is (202) 566-1744, and the telephone number for the Air Docket is (202) 566-1742. Visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm> for additional information about the EPA's public docket.

In addition to being available in the docket, an electronic copy of this notice will be available on the World Wide Web (WWW). Following signature, a copy of this notice will be posted at the following address: <http://www2.epa.gov/cleanpowerplan/>.

FOR FURTHER INFORMATION CONTACT: Ms. Amy Vasu, Sector Policies and Programs Division (D205-01), U.S. EPA, Research Triangle Park, NC 27711; telephone number (919) 541-0107, facsimile number (919) 541-4991; email address: vasu.amy@epa.gov or Ms. Lisa Conner, Sector Policies and Programs Division (D205-01), U.S. EPA, Research Triangle Park, NC 27711; telephone number (919) 541-5060, facsimile number (919) 541-4991; email address: conner.lisa@epa.gov.

SUPPLEMENTARY INFORMATION:

Organization of This Document. The information presented in this notice is organized as follows:

- I. Background
 - A. Proposed Rule
 - B. Purpose of the Notice
- II. Additional Information on the Translation of Emission Rate-Based CO₂ Goals to Mass-Based Equivalents

I. Background

A. Proposed Rule

On June 18, 2014, under the authority of Clean Air Act (CAA) section 111(d), the EPA proposed emission guidelines for states to follow in developing plans to address greenhouse gas (GHG) emissions from existing fossil fuel-fired electric generating units (EGUs) (79 FR 34830). On October 28, 2014, the EPA also issued a supplemental proposal, "Carbon Pollution Emission Guidelines: Existing Stationary Sources in Indian Country and U.S. Territories; Multi-jurisdictional Partnerships" (79 FR 65481).

One of the main elements of the proposals is the establishment of emission rate-based CO₂ goals. To set these goals, the EPA analyzed practical and affordable strategies that states and utilities are already using to lower carbon pollution from the power sector. These strategies are incorporated into what the proposal describes as building blocks that comprise the best system of emission reduction (BSER).¹ These

strategies, which are already being deployed by states and companies across the country, include improvements in efficiency at carbon-intensive power plants; programs that enhance generation from, and spur private investments in, low emitting and renewable power sources; as well as programs that help homes and businesses use electricity more efficiently. The EPA has proposed goals for each state, area of Indian country and U.S. territory with affected EGUs, as a carbon intensity rate, in terms of CO₂ per megawatt-hour generated. In calculating the emission rate-based goal, the EPA also took into consideration the area's fuel mix, electricity market and numerous other factors. Thus, each goal reflects the unique conditions of each state, area of Indian country and U.S. territory. The proposed rule also provides flexibility by authorizing each implementing authority to demonstrate achievement of the goal using a mass-based metric that is equivalent to its emission rate-based CO₂ goal. With the proposed rule issued on June 18, 2014, the EPA issued a TSD that demonstrates one potential way to translate the rate-based goal to a mass-based equivalent.

B. Purpose of the Notice

Upon issuance of the proposed rule, the EPA continued the extensive outreach effort to stakeholders and members of the public that the EPA had engaged in for many months preceding the proposal. This outreach has provided opportunities for all jurisdictions with affected entities—both individually and in regional groups—as well as numerous industry groups and non-governmental organizations, to meet with the EPA and ask clarifying questions about, and give initial reactions to, the proposed components, requirements and timing of the rulemaking. This outreach has included individual meetings; attendance at conferences; webinars; conference calls; and other communications, during which the EPA has responded to hundreds of clarifying questions about the proposal and received numerous initial reactions in both oral and written form. This engagement has been designed to facilitate a better understanding of the rule by stakeholders so that they could provide more informed substantive comments for the EPA to consider for the final rule, as well as allow the EPA to consider stakeholders' initial reactions.

During these discussions, many of the states, in particular, emphasized the importance of having more information and clarity on how the proposed rate-

based goals could potentially be translated to a mass-based equivalent metric. Some states requested additional information about how they might calculate a mass-based equivalent metric, while other states requested that the EPA calculate and provide presumptive mass-based equivalent metrics.

The purpose of this notice is to share additional information regarding potential methods for determining the mass that is equivalent to the emission rate-based CO₂ goal that the EPA has proposed. With this notice, the EPA is also making available a TSD that provides detailed information to further inform and assist implementing authorities and stakeholders in understanding the proposal. This notice is consistent with the methodologies used to define BSER in the June 18, 2014, proposal and October 28, 2014 supplemental proposal and does not reflect any type of response to the comments that we have received to date. Readers should also note that the TSD, and the illustrative numbers presented therein, are based on the emission rate-based goals as proposed; any calculations of mass equivalents would naturally yield different results if the emission rate-based goals themselves were to change in the course of developing the final rule.

II. Additional Information on the Translation of Emission Rate-Based CO₂ Goals to Mass-Based Equivalents

In the proposed rule published on June 18, 2014, the EPA proposed a set of state-specific emission rate-based CO₂ goals (in pounds of CO₂ per megawatt-hour of electricity generated). In addition, the EPA issued emission rate-based CO₂ goals for areas of Indian country and U.S. territories with affected EGUs in a supplemental proposal on October 28, 2014. The proposals authorized each implementing authority to translate the form of the emission rate-based goal to a mass-based form (i.e., goals expressed in terms of total tons of CO₂ per year from affected sources), as long as the translated goal achieves the equivalent in stringency. Today's notice provides additional detail, and describes two potential methodologies for this translation. Today's notice is accompanied by a TSD titled "Translation of the Clean Power Plan Emission Rate-Based CO₂ Goals to Mass-Based Equivalents," which has been placed in the docket for the rule (Docket ID No. EPA-HQ-OAR-2013-0602). For purposes of illustrating two methodologies for potential use in making rate-to-mass translations,

¹ CAA sections 111(d)(1) and (a)(1) direct the EPA to define BSER as the basis for state plans to reduce CO₂ from the affected sources.

today's notice and accompanying TSD identify two sets of mass-based values for each state, area of Indian country and U.S. territory with affected EGUs that could be considered equivalent to the proposed rate-based goals, as discussed below: One that is based on historical emissions from existing sources, and a second that is based on historical emissions from existing sources *and* projected emissions that would result from demand growth that is reflected in generation at both existing and new sources in the event that an implementing authority may want to include new sources of generation in its compliance approach. Illustrative values for each state, area of Indian country and U.S. territory with affected EGUs (along with the underlying data) for each method are also presented in the TSD.

In the proposed rule, the EPA intended to afford a considerable amount of flexibility in choosing the types of programs and measures needed to meet the goals established by the rulemaking. An important proposed element of this flexibility is allowing each implementing authority to demonstrate compliance with its interim and final rate-based goals established in the proposal, or to establish equivalent mass-based metrics for purposes of demonstrating compliance with the provisions of the rule. The agency recognizes that implementing authorities can use a mix of measures and programs to meet their goals regardless of which form of the standard they choose to use to demonstrate compliance in the state plan, including both programs that use mass-based metrics, as well as measures that use rate-based measures. State plans submitted to the EPA will be required either to (i) demonstrate that their programs and measures meet the rate-based goals established by the rulemaking, or (ii) if they choose to translate the rate-based goals into mass-based equivalents, demonstrate achievement of the goals using the mass-based metrics.²

In section VII of the preamble to the June 18, 2014 proposed rule, the EPA provides basic considerations necessary to translate the emission rate-based CO₂ goals into mass-based equivalents, for state plan purposes (79 FR 34897). The EPA also included in the docket for the

rule a TSD titled "Projecting EGU CO₂ Emission Performance in State Plans," that discusses the considerations, data and technical approaches that can be considered when converting the emission rate-based CO₂ goals into a mass-based equivalent metric, and focuses on one potential approach that implementing authorities could employ. The basic methodology presented in these documents is for the implementing authority to project for a given period the amount of generation by affected entities; to determine the amount of tons of CO₂ that would be emitted by affected EGUs; and to assure that the ratio of affected EGU emissions to affected entity generation is equivalent to the emissions performance of the rate-based goal.

The data, assumptions and methodological choices used for the estimation of generation by affected entities are of central importance for translation to a mass-based metric.³ For instance, uncertainties about future demand, the future inventory of EGUs and the relative amounts of generation among EGUs in light of, for example, fuel costs can influence the translation to a mass-based equivalent.

In response to requests by states, we are issuing this notice and the TSD, "Translation of the Clean Power Plan Emission Rate-Based CO₂ Goals to Mass-Based Equivalents," to present information about potential methods for translating the rate-based goals to mass-based equivalents. The TSD presents two additional possible methods for calculating mass-based equivalent metrics, the underlying data and shows the mass-based equivalent metric. The first method, based on historical data, produces mass-based equivalent metrics that apply to existing affected EGUs only. The second method, based on a combination of historical data and a projection of future electric demand, produces mass-based equivalent metrics that are inclusive of new fossil fuel-fired sources, in light of the fact that the rule takes comment on the inclusion of new, fossil fuel-fired sources as a component of state plans. As the starting point for these calculations, we use the proposed emission rate-based CO₂ goals set forth in the rulemaking. Also, to maintain consistency with the proposed rule, the calculations contain the same generation data used in setting the rate-

based goals (i.e., 2012 eGRID data for historical generation, and Annual Energy Outlook 2013 for regional growth estimates) to project future levels of generation.⁴

The EPA is providing this additional information to states, U.S. territories, tribes, and other stakeholders to provide a better understanding of the proposed rule. It should be reiterated that the mass-based equivalent metrics presented in the TSD are not required mass-based emission limits that implementing authorities must meet; rather, they are illustrations of two potential options that implementing authorities may choose to adopt if they choose to use a mass-based form of the emission rate-based goal. The EPA presents them to provide stakeholders a better understanding of the methodology and mass outcomes associated with two possible ways of calculating mass-based equivalent metrics.

Dated: November 6, 2014.

Janet G. McCabe,

Acting Assistant Administrator, Office of Air and Radiation.

[FR Doc. 2014-26900 Filed 11-12-14; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 141

[EPA-HQ-OW-2012-0155; FRL-9918-96-OW]

Notice of Public Meeting and Webinar: Preliminary Regulatory Determinations for the Third Contaminant Candidate List

AGENCY: Environmental Protection Agency.

ACTION: Notice of public meeting on potential rulemaking.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is announcing a public meeting and webinar to discuss the agency's preliminary determinations on whether or not to develop drinking water regulations for five unregulated contaminants listed on the third Contaminant Candidate List (CCL3). The EPA published and requested public

² Note that the metric for compliance is independent from the approaches that implementing authorities may adopt to achieve them. For example, a state could potentially adopt a mass-based program that achieves a rate-based goal, or adopt rate-based standards and/or other measures and demonstrate that they have met the goal using a mass-based metric.

³ Some stakeholders have observed that addressing potential translation to a mass equivalent could incorporate generation from "affected entities" that include generators beyond "affected EGUs." The proposal invited comment on how generation across "affected entities" (including at "affected EGUs") should be considered when calculating mass equivalents.

⁴ The Agency has received comments from some states about the accuracy of the 2012 data, as well as whether we should use more than a single year of data to determine the rate-based goals. We are reviewing all comments, information, and requests for data corrections received to date and will continue reviewing stakeholder input submitted to the docket by the close of the public comment period. Any changes to the emission rate-based goals and underlying data will be reflected in the final rule.

comment on its preliminary regulatory determinations of these five contaminants in the **Federal Register** (FR) on October 20, 2014. In that FR document, the agency announced its preliminary determinations to regulate one contaminant (i.e., strontium) and to not regulate four contaminants (i.e., 1,3-dinitrobenzene, dimethoate, terbufos and terbufos sulfone). On December 9, 2014, EPA will hold a public meeting and webinar to present and solicit public input on the process to identify, and the information used to evaluate, contaminants for the third Regulatory Determination effort; and the preliminary regulatory determinations for the aforementioned five unregulated contaminants listed on CCL3, including the supporting rationale for these determinations.

DATES: The public meeting and webinar will be held on Tuesday, December 9, 2014, from 1 p.m. to 5 p.m., eastern time. Persons wishing to attend the meeting in person or online via webinar must register by December 2, 2014, as described in the **SUPPLEMENTARY INFORMATION** section.

ADDRESSES: The public meeting will be held at The Cadmus Group, Inc., third floor conference room, located at 1555 Wilson Blvd., Suite 300, Arlington, VA 22209. All attendees must show government-issued photo identification (e.g., a driver's license) when signing in. This meeting will also be simultaneously broadcast as a webinar, available on the Internet.

FOR FURTHER INFORMATION CONTACT: Members of the public who wish to receive further information about the meeting and webinar or have questions about this notice should contact Ali Arvanaghi, Standards and Risk Management Division, Office of Ground Water and Drinking Water, Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Mail Code 4607M, Washington, DC 20460; telephone number: (202) 564-1260; email address: arvanaghi.ali@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. How may I participate in this meeting?

Persons wishing to attend the meeting in person or online via the webinar must register in advance no later than 5 p.m., eastern time on December 2, 2014, by sending an email to RD3Webinar@cadmusgroup.com. Those who wish to attend should indicate in the email whether they intend to attend in person or via the webinar. The number of seats and webinar connections available for

the meeting is limited and will be available on a first-come, first-served basis. The agenda for the public meeting and webinar will include time for public involvement and will allow for questions and answers or comments about the agency's third Regulatory Determination process and its preliminary regulatory determinations. If individuals or organizations are interested in making a more in-depth statement or presenting information, that interest should be mentioned when registering for the meeting. All statements or presentation materials should be emailed to RD3Webinar@cadmusgroup.com by December 2, 2014, so that the information can be incorporated into the webinar. We ask that only one person present the statement on behalf of a group or organization, and that the statement be limited to five minutes. Any additional comments, statements or information from attendees will be taken if time permits during the meeting or can be sent to RD3Webinar@cadmusgroup.com after the meeting, but before the close of the public comment period for the October 20, 2014, FR notice (79 FR 62716). It is important to remember that formal comments about the EPA's Preliminary Regulatory Determinations for Contaminants on the Third Drinking Water Contaminant Candidate List should be submitted to the docket (EPA-HQ-OW-2012-0155), as instructed in the October 20, 2014, FR notice, before the close of the public comment period on December 19, 2014.

B. How can I get a copy of the meeting and webinar materials?

The 508-compliant meeting materials will be sent by email to the registered attendees prior to the meeting. Information about registration and participation in the public meeting and webinar can be found on the EPA's Contaminant Candidate List 3 Web site: <http://water.epa.gov/scitech/drinkingwater/dws/ccl/ccl3.cfm>.

II. Background

The 1996 Safe Drinking Water Act Amendments require EPA to determine whether to regulate at least five unregulated contaminants from the current Contaminant Candidate List (CCL) with national primary drinking water regulations every five years. The process of making decisions about whether to regulate any of the CCL unregulated contaminants is called Regulatory Determination. On October 8, 2009 (74 FR 51850), EPA published the CCL3 containing 116 unregulated contaminants. On October 20, 2014 (79 FR 62716), EPA announced and

solicited public comment on its preliminary determinations to regulate one contaminant (i.e., strontium) and to not regulate four contaminants (i.e., 1,3-dinitrobenzene, dimethoate, terbufos and terbufos sulfone). The public comment period for the October 20, 2014, FR announcement, Preliminary Regulatory Determinations for Contaminants on the Third Drinking Water Contaminant Candidate List, closes on December 19, 2014. After considering public comments and any additional information, EPA expects to publish the final, third Regulatory Determination in late 2015.

Dated: October 31, 2014.

Peter Grevatt,

Director, Office of Ground Water and Drinking Water.

[FR Doc. 2014-26573 Filed 11-12-14; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY REGION 8

[FRL-9919-11-Region-8]

40 CFR Part 503

Propose and Modify NPDES General Permits for Facilities That Generate, Treat, and/or Use/Dispose of Sewage Sludge by Land Application, Landfill and Surface Disposal in the EPA Region 8

AGENCY: The Environmental Protection Agency.

ACTION: Notice of proposed and final modification of the expiration date of the eleven (11) NPDES general permits for Sewage Sludge.

SUMMARY: The Environmental Protection Agency (EPA) is giving notice of modification of the expiration date of the National Pollutant Discharge Elimination System (NPDES) general permits for facilities or operations that generate, treat, and/or use/dispose of sewage sludge by means of land application, landfill and surface disposal in the states of Colorado, Montana, North Dakota, and Wyoming and in Indian country in the states of Colorado, Montana, North Dakota, South Dakota, Wyoming and Utah (except for the Goshute Indian Reservation and the Navajo Indian Reservation) from May 12, 2018, to January 15, 2015. The EPA will regulate sewage sludge (biosolids) through the direct enforceability provision of the regulation.

DATES: This comment period closes on December 15, 2014. *Comments may be directed to:* Bob Brobst (8P-W-WW),

EPA Region 8, 1595 Wynkoop Street, Denver, Colorado 80202-1129. All comments received prior to the end of the comment period will be considered in the formulation of the final permit decision.

After considering these comments, the EPA will issue the final permit decision together with written responses to any significant comments, in accordance with 40 CFR 124.15. If no comments are received, the modification of the 11 permits will be effective immediately upon issuance of the final permit decision.

ADDRESSES: The administrative record is available by appointment for review and copying at the EPA Region 8 offices during the hours of 8:00 a.m. to 4:00 p.m., Monday through Friday, Federal holidays excluded.

To make an appointment to look at or copy the documents call Bob Brobst at (303) 312-6129. The Region 8 offices are located at 1595 Wynkoop Street, Denver, Colorado 80202-1129. A

reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT:

Additional information concerning the final permits may be obtained from Bob Brobst, EPA Region 8, Wastewater Unit (8P-W-WW), 1595 Wynkoop Street, Denver, Colorado 80202-1129, telephone (303) 312-6129 or email at brobst.bob@epa.gov.

The final general permits, the fact sheet and additional information may be downloaded from the EPA Region 8 Web page at <http://www2.epa.gov/region8/biosolids>. Please allow one week after date of this publication for items to be uploaded to the Web page.

SUPPLEMENTARY INFORMATION: The EPA proposes to change the expiration date from May 12, 2018, to January 15, 2015. No other changes will occur in the general permits. The Federal Sewage Sludge Regulations gives the permitting authority, in this case the EPA Region 8, the choice of either issuing a permit or relying on direct enforceability of the regulation.

Direct enforceability means that no person shall use or dispose of sewage sludge through any practice for which requirements are established in the Federal Sewage Sludge Regulation, except in accordance with such requirements.

The EPA Region 8 has decided, for administrative reasons, to regulate sewage sludge (biosolids) through the direct enforceability provision of the regulation. In accordance with 40 CFR 503.3, the permitting authority, in this case the EPA Region 8, may either issue a permit or rely on direct enforceability of the 40 CFR 503. The EPA Region 8 has elected to administer the program under the direct enforceability provision.

The Federal Sewage Sludge Regulations referred to above in the summary section are located at 40 CFR 503 specifically at 40 CFR 503.3. (See <http://www.ecfr.gov/>) The NPDES permit numbers and the areas covered by this modification of the eleven (11) general permits are listed below.

State	Permit No.	Area covered by each general permit
Colorado	COG650000	State of Colorado, except for Federal Facilities and Indian country.
	COG651000	Indian country within the State of Colorado and the portions of the Ute Mountain Indian Reservation located in New Mexico and in Utah.
	COG652000	Federal Facilities in the State of Colorado, except those located in Indian country, which are covered under permit COG51000.
Montana	MTG650000	State of Montana, except for Indian country.
	MTG651000	Indian country in the State of Montana.
North Dakota	NDG650000	State of North Dakota, except for Indian country.
	NDG651000	Indian country within the State of North Dakota, except for Indian country located within the former boundaries of the Lake Traverse Indian Reservation, which are covered under permit SDG651000, and that portion of the Standing Rock Indian Reservation located in South Dakota.
South Dakota	SDG651000	Indian country within the State of South Dakota, except for the Standing Rock Indian Reservation, which is covered under permit NDG651000, and that portion of the Pine Ridge Indian Reservation located in Nebraska and Indian country located in North Dakota within the former boundaries of the Lake Traverse Indian Reservation.
Utah	UTG651000	Indian country within the State of Utah, except for the Goshute Indian Reservation, Navajo Indian Reservation and Ute Mountain Indian Reservation, which are covered under permit COG651000.
Wyoming	WYG650000	State of Wyoming, except for Indian country.
	WYG651000	Indian country within the State of Wyoming.

Other Legal Requirements

Section 401(a)(1) Certification: Since this modification does not involve discharges to waters of the United States, certification under § 401(a)(1) of the Clean Water Act is not necessary.

Economic Impact (Executive Order 12866): The EPA has determined that the modification of these general permits is not a “significant regulatory action” under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993).

Paperwork Reduction Act: The information collection requirements for

this modification will not differ in the proposed permits.

Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA): The RFA requires that the EPA prepare a regulatory flexibility analysis for rules subject to the requirements of 5 U.S.C. 553(b). The modification of the permits proposed today is not a “rule” subject to the requirements of 5 U.S.C. 553(b) and is therefore not subject to the RFA.

Unfunded Mandates Reform Act: The modification of the permits proposed

today is not a “rule” subject to the RFA and is therefore not subject to the requirements of UMRA.

Authority: 33 U.S.C. 1251 *et seq.*

Dated: October 29, 2014.

Callie A. Videtich,

*Acting Assistant Regional Administrator,
Office of Partnerships and Regulatory
Assistance, Region 8.*

[FR Doc. 2014-26898 Filed 11-12-14; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Parts 600 and 622**

[Docket No. 080225276–4124–01]

RIN 0648–AS65

Fisheries of the Caribbean, Gulf, and South Atlantic; Aquaculture

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: NMFS reopens the comment period on the proposed rule to implement the Fishery Management Plan for Regulating Offshore Aquaculture in the Gulf of Mexico (FMP) that published on August 28, 2014. The original comment period closed on October 27, 2014. NMFS is reopening the comment period for an additional 15 days to provide the public additional time to comment on this proposed rule. If implemented, the proposed rule would establish a comprehensive regulatory program for managing the development of an environmentally sound and economically sustainable aquaculture industry in Federal waters of the Gulf of Mexico (Gulf). The purpose of the proposed rule is to increase the yield of Federal fisheries in the Gulf by supplementing the harvest of wild caught species with cultured product.

DATES: The comment period for the proposed rule that published on August 28, 2014 (79 FR 51424), and closed on October 27, 2014, will reopen on November 13, 2014 and remain open through November 28, 2014.

ADDRESSES: You may submit comments on the proposed rule, identified by

“NOAA–NMFS–2008–0233,” by any of the following methods:

- Electronic Submissions: Submit electronic public comments via the Federal e-Rulemaking Portal. Go to www.regulations.gov/#/docketDetail;D=NOAA-NMFS-2008-0233, click the “Comment Now!” icon, complete the required fields, and enter or attach your comments.
- Mail: Submit written comments to Jess Beck-Stimpert, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on www.regulations.gov without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter “N/A” in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

Electronic copies of the FMP, which includes a final programmatic environmental impact statement (FPEIS), an initial regulatory flexibility analysis (IRFA), and a regulatory impact review (RIR) may be obtained from the Southeast Regional Office Web site at <http://sero.nmfs.noaa.gov>.

Comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule may be submitted in writing to Anik Clemens, Southeast Regional Office, NMFS, 263 13th Ave. South, St. Petersburg, FL 33701; and the Office of Management

and Budget (OMB), by email at OIRASubmission@omb.eop.gov, or by fax to 202–395–7285.

FOR FURTHER INFORMATION CONTACT: Jess Beck-Stimpert, 727–824–5301.

SUPPLEMENTARY INFORMATION:

Aquaculture in the Gulf will be managed under the FMP. The FMP was prepared by the Council and is being implemented through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

On August 28, 2014, NMFS published a proposed rule to implement the FMP to authorize the development of commercial aquaculture operations in Federal waters of the Gulf (79 FR 51424). The FMP provides a comprehensive framework for authorizing and regulating offshore aquaculture activities. The FMP also establishes a programmatic approach for evaluating the potential impacts of proposed aquaculture operations in the Gulf.

NMFS received several requests from the public to extend the comment period of the proposed rule. Due to the extensive nature of the FMP and the proposed rulemaking, NMFS is reopening the comment period on the proposed rule for an additional 15 days. Comments submitted during the prior comment period will be incorporated into the public record and will be fully considered during the preparation of the final rule.

Authority: 5 U.S.C. 561 and 16 U.S.C. 1801 *et seq.*

Dated: November 4, 2014.

Samuel D. Rauch III,
*Deputy Assistant Administrator for
Regulatory Programs, National Marine
Fisheries Service.*

[FR Doc. 2014–26801 Filed 11–12–14; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 79, No. 219

Thursday, November 13, 2014

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

November 7, 2014.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by December 15, 2014 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW., Washington, DC 20503. Commenters are encouraged to submit their comments to OMB via email to: OIRA_Submission@omb.eop.gov or fax (202) 395-5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250-7602. Copies of the submission(s) may be obtained by calling (202) 720-8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control

number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

National Agricultural Statistics Service

Title: Organic Survey.

OMB Control Number: 0535-0249.

Summary of Collection: The primary objective of the National Agricultural Statistics Services (NASS) is to prepare and issue State and national estimates of crop and livestock production, prices, and disposition as well as economic statistics, farm numbers, land values, on-farm pesticide usage, pest crop management practices as well as the Census of Agriculture. General authority for these data collection activities is granted under 7 U.S.C. 2204. This census of organic farmers is required by law under the "Census of Agriculture Act of 1997," Pubic Law 105-113, 7 U.S.C. 2204(g), as amended. Response to this survey will be mandatory.

Need and Use of the Information: The information is vital to RMA in determining insurance payments to organic farmers. The Organic Survey will provide acreage, production, and sales data for a variety of organic crop and livestock commodities as well as to gather information on organic marketing practices. These data will be provided by certified organic farms, organic farms exempt from certification, and transitional farms in all 50 States. National and State estimates (where publishable) will be set for all items that are collected on the survey. The collected data will be used to enhance programs like the Environmental Quality Incentives Program (EQIP) by providing accurate, detailed data for agricultural products produced using organic practices.

Description of Respondents: Farmers and Ranchers.

Number of Respondents: 17,500.

Frequency of Responses: Reporting: One time.

Total Burden Hours: 13,586.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2014-26911 Filed 11-12-14; 8:45 am]

BILLING CODE 3410-20-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2014-0083]

Notice of Request for Extension of Approval of an Information Collection; Importation of Mangoes From Australia

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request an extension of approval of an information collection associated with the regulations for the importation of mangoes from Australia.

DATES: We will consider all comments that we receive on or before January 12, 2015.

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0083>.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2014-0083, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0083> or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the importation of mangoes from Australia, contact Ms. Nicole Russo, Assistant Director, RCC, RPM, PHP, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737; (301) 851-2159. For copies of more detailed information on the information collection, contact Ms. Kimberly Hardy,

APHIS' Information Collection Coordinator, at (301) 851-2727.

SUPPLEMENTARY INFORMATION:

Title: Importation of Mangoes From Australia.

OMB Control Number: 0579-0391.

Type of Request: Extension of approval of an information collection. *Abstract:* The Plant Protection Act (PPA, 7 U.S.C. 7701 *et seq.*) authorizes the Secretary of Agriculture to restrict the importation, entry, or interstate movement of plants, plant products, and other articles to prevent the introduction of plant pests into the United States or their dissemination within the United States. Regulations authorized by the PPA concerning the importation of fruits and vegetables into the United States from certain parts of the world are contained in "Subpart—Fruits and Vegetables" (7 CFR 319.56–1 through 319.56–71).

In accordance with § 319.56–60, mangoes from Australia are subject to certain conditions before entering the United States to ensure that plant pests are not introduced into the United States. Among other things, the regulations require an information collection activity consisting of a phytosanitary certificate. Each shipment of mangoes must be accompanied by a phytosanitary certificate issued by the national plant protection organization of Australia with an additional declaration that the mangoes were inspected prior to export and found free of certain pests and treated in accordance with the regulations.

We are asking the Office of Management and Budget (OMB) to approve our use of this information collection activity for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; e.g., permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 0.5 hours per response.

Respondents: National plant protection organization of Australia.

Estimated annual number of respondents: 20.

Estimated annual number of responses per respondent: 5.

Estimated annual number of responses: 100.

Estimated total annual burden on respondents: 50 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 6th day of November 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2014-26853 Filed 11-12-14; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S-132-2014]

Foreign-Trade Zone 231—Stockton, California; Application for Subzone; 5.11, Inc.; Modesto and Lathrop, California

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the Port of Stockton, grantee of FTZ 231, requesting subzone status for the facilities of 5.11, Inc., located in Modesto and Lathrop, California. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on November 6, 2014.

The proposed subzone would consist of the following sites: *Site 1* (5.22 acres) 4300 Spyres Way, Modesto; and *Site 2* (5 acres) 17610 Shideler Parkway, Lathrop. No authorization for production activity has been requested at this time. The proposed subzone would be subject to the existing activation limit of FTZ 231.

In accordance with the FTZ Board's regulations, Christopher Kemp of the FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is December 23, 2014. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to January 7, 2015.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230-0002, and in the "Reading Room" section of the FTZ Board's Web site, which is accessible via www.trade.gov/ftz.

For further information, contact Christopher Kemp at christopher.kemp@trade.gov or (202) 482-0862.

Dated: November 6, 2014.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2014-26891 Filed 11-12-14; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S-119-2014]

Approval of Subzone Status; Kinder Morgan Operating L.P. "C"; Hawesville, Kentucky

On September 10, 2014, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the Louisville & Jefferson County Riverport Authority, grantee of FTZ 29, requesting subzone status subject to the existing activation limit of FTZ 29, on behalf of Kinder Morgan Operating L.P. "C", in Hawesville, Kentucky.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (79 FR 56058, 9-18-2014). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval. Pursuant to the authority delegated to the FTZ Board Executive Secretary (15 CFR Sec. 400.36(f)), the application to establish Subzone 29M is approved, subject to the FTZ Act and the Board's regulations, including Section 400.13, and further subject to FTZ 29's 2,000-acre activation limit.

Dated: November 7, 2014.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2014-26890 Filed 11-12-14; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B-80-2014]

Foreign-Trade Zone (FTZ) 127—West Columbia, South Carolina; Notification of Proposed Production Activity; Komatsu America Corporation (Material Handling, Construction and Forestry Machinery); Newberry, South Carolina

Komatsu America Corporation (Komatsu) submitted a notification of proposed production activity to the FTZ Board for its facility in Newberry, South Carolina, within FTZ 127. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on October 28, 2014.

The Komatsu facility is located within Site 3 of FTZ 127. The facility is used for the production of wheel loaders and forklift trucks, but may produce other material handling, construction and forestry machinery in the future, such as bulldozers, angledozers, hydraulic excavators, forestry harvesters, forestry feller bunchers, dump trucks (duty-free) and forestry forwarders. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status materials and components and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt Komatsu from customs duty payments on the foreign status components and materials used in export production. On its domestic sales, Komatsu would be able to choose the duty rates during customs entry procedures that apply to fork-lift trucks, wheel loaders, bulldozers, angledozers, hydraulic excavators, forestry harvesters, forestry feller bunchers, dump trucks (duty-free) and forestry forwarders (duty rate 25%) for the foreign status inputs noted below. Customs duties also could possibly be deferred or reduced on foreign status production equipment.

The components and materials sourced from abroad include: Paints; plastic hoses; hose joints; adhesive decals; plastic tags; plastic washers; plastic rings; plastic seals; plastic packings; plastic bands; PVC electric

terminal caps; plastic clamps; plastic clips; rubber foam sheets; sponges; rubber pads w/adhesive; rubber weather strip; rubber weather strip seals; rubber hoses no fitting; rubber tubes; rubber hoses w/fittings not reinforced; rubber hoses w/fittings cover w/metal wire; rubber hoses reinforced w/textile; rubber hoses w/fittings reinforced; rubber hoses no fittings reinforced; rubber hoses for construction equipment; rubber hoses w/fittings cover w/metal wire & textile; molded rubber hoses; fan belts; alternators; v-belts reinforced w/textile; wheel loader tires; forklift tires; rubber floor mats; rubber grommets; rubber dust seals; rubber gaskets; rubber o-rings; rubber pads, no adhesive; rubber seals; rubber blocks; rubber caps; rubber clamps; rubber cushions; damper, operators compartment; rubber guards; cork plugs; glass wool; mirror for wheel loaders; sheet, fiber glass-heat resistant; elbows, alloy/cast/threaded; tees, alloy/cast/threaded; unions; flange hoses, alloy; elbows, tube non alloy; connectors, non-alloy steel fitting; quick couplers; steel wire ropes; chains for wheel loaders; screws for forklift; bolts, hex head, no nut; SEMS bolt and washer assemblies; screws, Phillip, no nut; nuts, hex head; bolts, hex head w/nut; screws w/nut; u-bolts w/nut; studs; nuts, steel for forklift; nuts, general application; washers, iron helical spring; washers, alloy; rivets; cotter pin clips; keys, steel; dowel pins not threaded; pins, metal, not threaded; helical springs; bands, hose/tube holders; metal clamps, hose holders; clips, hose/tube holder; plastic holders; elbows, brass, threaded; washers, brass; aluminum nuts; aluminum clamps, not threaded; steel clamps for forklift; keys, steel with padlock; lock assemblies; metal hinges for wheel loaders; handrails for wheel loaders; clips, alloy w/rubber coating; clips, electric wiring; springs, pneumatic cylinder; locks, metal latches; wheel loader consoles; name plates, vinyl; engines for wheel loaders; engines for forklifts; plugs, oil pan & suction tubes, steel; tilt cylinders for forklifts; cylinders for wheel loaders; motor assemblies for wheel loaders; shims, round, steel; fuel pumps; hydraulic pump assemblies; hydraulic gear pumps; couplings, hydraulic pump part; compressor assembly parts; air compressor collars; A/C receiver dryers; strainers, fuel filter; filter assemblies; air cleaner assemblies; diesel particle filter assemblies; cap, air cleaner, plastic; fire extinguisher assemblies; washer tank assemblies; axles for forklifts; bands, electric system; bars, for forklift counterweights; bonnets for forklifts;

breathers, hydraulic system; clips for forklifts; collars for forklifts; control valves for forklifts; counterweights for forklifts; covers, electrical system, forklifts; damper stays, bonnet for forklifts; dashboard covers; dual tire spacers for forklifts; engine accessories for forklifts; fitting assemblies for forklifts; floors, steel plate; forklift main frames; forklift radiators; fuse holders; LPG fitting kits; ground straps; head guard assemblies for forklifts; hub & knuckle for forklifts; knob, operator compartment for forklifts; lever, steel for forklifts; light, LED w/switch; lights for forklifts; lock pin for forklifts; liquefied petroleum tanks for forklifts; metal bracket/block for forklifts; metal cap for forklifts; metal plug for forklifts; meter panels; mirrors for forklifts; mounts, engine mounting parts; mounting cushions for forklifts; mufflers; mufflers for forklifts; operator fans for forklifts; operator seats for forklifts; pedal assemblies; pins for forklifts; pipes for forklifts; radiators; reserve tank assemblies; rims for forklifts; shaft steering, steering columns for forklifts; shroud kits for forklifts; solenoid valves for forklifts; sponges, insulators for forklift frames; standard forks for forklifts; steel brackets for forklift lights; steel plates for forklifts; steel shims for forklifts; steering wheels for forklifts; sub-counterweights for forklifts; support brackets for forklift frames; tire spacers for forklifts; tire/rim assemblies for forklifts; tubes for forklifts; front buckets for wheel loaders; cylinders, bucket for wheel loaders; three valve lever consoles; adapters, hoses; additional counterweights for wheel loaders; air cleaners; axles for wheel loaders; bands, cab washer tanks; bands, threaded nuts; bar locks; battery cables; beacons; bellcranks for wheel loaders; machined metal blocks; blocks, hydraulic pumps; boom assemblies for wheel loaders; brackets, welded, steel; buckets for wheel loader; bushings, metal, multi application; cabs for wheel loaders; caps, radiator; caps, rubber, multiple purposes; catches; clamps; clamps, steel plate, multiple purposes; clips; collars, steel, for hinge pins; connectors; cool & heat boxes; counterweights; counterweights for wheel loaders; coupler assemblies for wheel loaders; couplings; covers, plastic for wheel loader; cushions, multiple application; cutting edges for buckets; cylinder assemblies; dashboards; decals; deflectors steel cover; doors for wheel loaders; elbows; elbows alloy/cast; elbows, main valves; elbows, steel, thread cast; fasteners; fenders, metal; finishers; flanges, hoses/metal/fittings; floors, metal sheets; foam sheets; frames,

steel parts for wheel loaders; front frame assemblies for wheel loaders; front frame subassemblies for wheel loaders; fuel tank assemblies; fuel tanks for wheel loaders; function kits; grilles, radiators; grips; guards, steel; guides, hydraulic tank for wheel loaders; hand rails, steel; hinge pins, steel, not threaded; holders, steel brackets; hood assemblies for wheel loaders; hood kits for wheel loaders; hoods, metal sheet parts for wheel loaders; hydraulic tanks for wheel loaders; joints, hoses, alloy/ threaded; joystick steering kits; knobs, fuel container levers, plastic; ladders, steel for wheel loaders; levers for wheel loaders; link assemblies, steel for bellcranks; loader controls for wheel loaders; lock bars; marks, waste handlers; metal blocks, seats; metal ladders; metal rods; metal rods for wheel loaders; multifunction lever consoles; mufflers for wheel loaders; nipples alloy piping; nipples tubes; nipples, hoses, steel threaded; oil coolers; operator seats for wheel loaders; pads; side panels; welded metal pipe assemblies; steel plates for wheel loaders; plates, vinyl adhesive; cork plugs, multiple uses; plugs for hydraulic tanks; plugs, fender; plugs, for wheel loaders; plugs, hoses, multiple application; plugs, miscellaneous uses; pre separators; radiator and grille assemblies; radiator and grille kits; rear battery relays; rear console covers; rear frame assemblies; rear frame assemblies for wheel loaders; rear underguards; retainers; rim assemblies for wheel loaders; cabs for wheel loaders; rubber hydraulic piping; seals; seat belts; seats, steel block motor/vehicle; seats, steel, multiple uses for wheel loaders; shafts for wheel loaders; shims, for front feeder systems; shims, steel; slack adjusters; sleeve/heads, not fitting multiple application; solenoid valves; sound absorption sheets for wheel loaders; spacers for air cleaner connect; spacers for brake piping; spacers, multiple application, metal, alloy; spring bars; step assemblies for wheel loaders; stoppers, multiple application for wheel loaders; strikers, hood door for wheel loaders; metal supports; supports, axle for wheel loaders; swivels; tanks, radiator reservoirs; tees, hoses, alloy/ cast/threaded; tees, no hose/tube alloy-cast; third function jumper kits; tool boxes for wheel loaders; tooth kits, castings for wheel loader buckets; trim; tubes, alloy w/fitting for wheel loader; underguards; unions, hose, multiple application; unions, no hose/tube steel; ventilators; viscous mounts for wheel loader cabs; washers/spacers for wheel loaders; wedges; accumulators for forklifts; accumulators for wheel

loaders; valve assemblies, pressure reducers, hydraulic; valve assemblies, pressure reducers, pneumatic; valves, brake control; control valves for wheel loaders; valve, plastic; check valves; valve assemblies, safety relief; solenoid valves; valves, check steel gates; band, control bands for forklifts; collars, main valve no fitting; covers, control valve for forklifts; knobs, control valves; lever subassemblies; nipples, valve part; orifices; plugs, control valves; poppets; shafts, control valve for forklifts; tubes, control valve; unions, control valves; union, pump hoses; bearings, radial ball; bearings, thrust; bearings, taper roller; bearings, needle; propeller shaft, drive shaft; bearings, flange housed; bushings, plain shaft bearings; thrust washers, plastic plain shaft; rear axle assemblies; transfer case assemblies for wheel loaders; transmission assemblies for forklifts; transfer case assemblies for wheel loaders; transmission assemblies; pulleys for forklifts; coupling assemblies for wheel loaders; axle assemblies; drive axles; axle assemblies for wheel loaders; ring gears, damper; transmissions for wheel loaders; collars, transmission fitting for wheel loader; couplings, not fit, damper, wheel loaders; deflectors, drive shaft; elbows for torque/ transmission; holders for drive shaft; shims for drive shaft; packing for forklifts; rubber seals reinforce w/metal; steel grease fittings; seals, rubber reinforced w/metal & plastic; seals, rubber reinforcers w/metal & textile; torque converters; wet batteries for wheel loaders; wet batteries for forklifts; batteries, lead acid; switch 3 pins; metal holders; rear view cameras; radio AM/FM for wheel loaders; travel alarms; blinker brackets; button horns; buzzers, electrical system; flashers and holders; front light assemblies; lamps, back up; strobe lights; resistor assemblies for wheel loaders; resistor assemblies for forklifts; fuses, plastic & copper; relays, electric system; battery disconnect switches; pressure switches; switches, rocker; connectors, electrical; covers, battery wiring; fuse holders; terminals, brass, battery; engine controllers; caps, rubber, wiring harness, battery; head lights; rear lead lamps; light fuse harnesses; light stay harnesses; working lamps; covers, head lamp parts; switch timers; cables, battery; wiring harnesses for wheel loaders; cables, electrical system; cables for harness/battery; light harnesses; engine harnesses; bands, cab washer tanks; welded machined metal block assemblies; seats, steel block motor/vehicle; caps, radiator; clamps, steel plates, multiple purposes; elbows alloy/cast; front frame subassemblies for wheel loaders; metal ladders; viscous

mounts for wheel loader cabs; nipples, alloy piping; plugs, cork multiple uses; spacers for brake piping; sensor assemblies, engine wiring; sensors, temperature; gauges, dipstick; sensors for floor frame wheel loaders; oil level gauges; pressure airflow sensors; sensors, switch; sensors for torque converter/transmission; sensors for boom; dome lights; dome light brackets; and, dome light harnesses (duty rates range from free to 12.5%).

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is December 23, 2014.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230-0002, and in the "Reading Room" section of the FTZ Board's Web site, which is accessible via www.trade.gov/ftz.

For further information, contact Diane.Finver@trade.gov or (202) 482-1367.

Elizabeth Whiteman,
Acting Executive Secretary.

[FR Doc. 2014-26889 Filed 11-12-14; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-865]

Certain Hot-Rolled Carbon Steel Flat Products From the People's Republic of China: Final No Shipments Determination of Antidumping Duty Administrative Review; 2012-2013

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On July 30, 2014, the Department of Commerce (the "Department") published the *Preliminary Results* of the 2012-2013 administrative review of the antidumping duty order on certain hot-rolled carbon steel flat products ("hot-rolled steel") from the People's Republic of China ("PRC").¹ The period of review ("POR") is November 1, 2012, through October 31, 2013. We received no comments from interested parties.

¹ See *Certain Hot-Rolled Carbon Steel Flat Products From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2012-2013*, 79 FR 44155 (July 30, 2014) ("*Preliminary Results*").

Therefore, the Department continues to find that Baosteel Group Corporation, Shanghai Baosteel International Economic & Trading Co., Ltd., and Baoshan Iron and Steel Co., Ltd. (collectively, “Baosteel”) had no reviewable transactions of subject merchandise to the United States during the POR.

DATES: *Effective Date:* November 13, 2014.

FOR FURTHER INFORMATION CONTACT:

Steven Hampton, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482-0116.

SUPPLEMENTARY INFORMATION:

Background

On July 30, 2014, the Department published the *Preliminary Results* of the administrative review of the antidumping duty order on hot-rolled steel from the PRC.² We invited interested parties to comment on the *Preliminary Results*. No party provided comments. The Department has conducted this administrative review in accordance with section 751(a)(1) of the Tariff Act of 1930, as amended (“the Act”).

Scope of the Order

The products covered by the order are certain hot-rolled carbon steel flat products of a rectangular shape, of a width of 0.5 inch or greater, neither clad, plated, nor coated with metal and whether or not painted, varnished, or coated with plastics or other non-metallic substances, in coils (whether or not in successively superimposed layers), regardless of thickness, and in straight lengths of a thickness of less than 4.75 mm and of a width measuring at least 10 times the thickness. Universal mill plate (*i.e.*, flat-rolled products rolled on four faces or in a closed box pass, of a width exceeding 150 mm, but not exceeding 1,250 mm, and of a thickness of not less than 4.0 mm, not in coils and without patterns in relief) of a thickness not less than 4.0 mm is not included within the scope of the order. Specifically included within the scope of the order are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (“IF”)) steels, high strength low alloy (“HSLA”) steels, and the substrate for motor lamination steels. IF steels are recognized as low carbon steels with micro-alloying levels of elements such

as titanium or niobium (also commonly referred to as columbium), or both, added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, vanadium, and molybdenum. The substrate for motor lamination steels contains micro-alloying levels of elements such as silicon and aluminum. Steel products included in the scope of the order, regardless of definitions in the Harmonized Tariff Schedule of the United States (“HTSUS”), are products in which: i) iron predominates, by weight, over each of the other contained elements; ii) the carbon content is two percent or less, by weight; and, iii) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

- 1.80 percent of manganese, or
- 2.25 percent of silicon, or
- 1.00 percent of copper, or
- 0.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 1.25 percent of nickel, or
- 0.30 percent of tungsten, or
- 0.10 percent of molybdenum, or
- 0.10 percent of niobium, or
- 0.15 percent of vanadium, or
- 0.15 percent of zirconium.

All products that meet the physical and chemical description provided above are within the scope of the order unless otherwise excluded. The following products, for example, are outside or specifically excluded from the scope of the order:

- Alloy hot-rolled steel products in which at least one of the chemical elements exceeds those listed above (including, *e.g.*, American Society for Testing and Materials (“ASTM”) specifications A543, A387, A514, A517, A506).
- Society of Automotive Engineers (“SAE”)/American Iron & Steel Institute (“AISI”) grades of series 2300 and higher.
- Ball bearing steels, as defined in the HTSUS.
- Tool steels, as defined in the HTSUS.
- Silico-manganese (as defined in the HTSUS) or silicon electrical steel with a silicon level exceeding 2.25 percent.
- ASTM specifications A710 and A736.
- USS abrasion-resistant steels (USS AR 400, USS AR 500).
- All products (proprietary or otherwise) based on an alloy ASTM specification (sample specifications: ASTM A506, A507).
- Non-rectangular shapes, not in coils, which are the result of having

been processed by cutting or stamping and which have assumed the character of articles or products classified outside chapter 72 of the HTSUS.

The merchandise subject to the order is classified in the HTSUS at subheadings: 7208.10.15.00, 7208.10.30.00, 7208.10.60.00, 7208.25.30.00, 7208.25.60.00, 7208.26.00.30, 7208.26.00.60, 7208.27.00.30, 7208.27.00.60, 7208.36.00.30, 7208.36.00.60, 7208.37.00.30, 7208.37.00.60, 7208.38.00.15, 7208.38.00.30, 7208.38.00.90, 7208.39.00.15, 7208.39.00.30, 7208.39.00.90, 7208.40.60.30, 7208.40.60.60, 7208.53.00.00, 7208.54.00.00, 7208.90.00.00, 7211.14.00.90, 7211.19.15.00, 7211.19.20.00, 7211.19.30.00, 7211.19.45.00, 7211.19.60.00, 7211.19.75.30, 7211.19.75.60, and 7211.19.75.90. Certain hot-rolled carbon steel flat products covered by the order, including: vacuum degassed fully stabilized; high strength low alloy; and the substrate for motor lamination steel may also enter under the following tariff numbers: 7225.11.00.00, 7225.19.00.00, 7225.30.30.50, 7225.30.70.00, 7225.40.70.00, 7225.99.00.90, 7226.11.10.00, 7226.11.90.30, 7226.11.90.60, 7226.19.10.00, 7226.19.90.00, 7226.91.50.00, 7226.91.70.00, 7226.91.80.00, and 7226.99.00.00. Subject merchandise may also enter under 7210.70.30.00, 7210.90.90.00, 7211.14.00.30, 7212.40.10.00, 7212.40.50.00, and 7212.50.00.00. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to the order is dispositive.

Final Determination of No Shipments

In the *Preliminary Results*, the Department preliminarily determined that Baosteel did not have any reviewable transactions of subject merchandise during the POR because there was no evidence on the record indicating that Baosteel had entries of subject merchandise during the POR.³ We stated, consistent with the refinement to the Department’s assessment practice in nonmarket economy (“NME”) cases, that we would not rescind the review in these circumstances but, rather, would complete the review with respect to Baosteel and issue appropriate instructions to U.S. Customs and Border Protection (“CBP”) based on the final results of the review.⁴ As stated above,

³ *Id.*, 79 FR at 44156.

⁴ *Id.*

² *Id.*

we did not receive any comments on the *Preliminary Results*. Therefore, we continue to determine that Baosteel had no reviewable transactions of subject merchandise during the POR. Consistent with our “automatic assessment” clarification, the Department will issue appropriate instructions to CBP based on our final results.⁵

Assessment

Upon issuance of the final results, the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries, in accordance with 19 CFR 351.212. The Department intends to issue assessment instructions to CBP 15 days after the date of publication of the final results of review. The Department announced a refinement to its assessment practice in NME cases.⁶ Pursuant to this refinement in practice, for entries that were not reported in the U.S. sales databases submitted by companies individually examined during this review, the Department will instruct CBP to liquidate such entries at the NME-wide rate. In addition, if the Department determines that an exporter under review had no shipments of the subject merchandise, any suspended entries that entered under that exporter’s case number (*i.e.*, at that exporter’s rate) will be liquidated at the NME-wide rate.⁷

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) for previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (2) for all PRC exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will be the PRC-wide rate of 90.83 percent; and (3) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporters that published that non-PRC

exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notifications

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary’s presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

In accordance with 19 CFR 351.305(a)(3), this notice also serves as a reminder to parties subject to administrative protective order (“APO”) of their responsibility concerning the return or destruction of proprietary information disclosed under APO, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing this administrative review and notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: November 4, 2014.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2014–26794 Filed 11–12–14; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–966]

Drill Pipe From the People’s Republic of China: Preliminary Results of Countervailing Duty Administrative Review; 2013

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review of the countervailing duty (CVD) order on drill pipe from the People’s Republic of China (PRC). The period of review (POR) is January 1, 2013, through December 31, 2013. We preliminarily determine that Shanxi Yida Special

Steel Imp. & Exp. Co., Ltd. and its cross-owned affiliates received countervailable subsidies during the POR.

DATES: *Effective Date:* November 13, 2014.

FOR FURTHER INFORMATION CONTACT:

Kristen Johnson, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–4793.

Scope of the Order

The scope of the order consists of steel drill pipe and steel drill collars, whether or not conforming to American Petroleum Institute (API) or non-API specifications. The merchandise subject to the order is currently classifiable under the Harmonized Tariff Schedule of the United States (HTSUS) categories: 7304.22.0030, 7304.22.0045, 7304.22.0060, 7304.23.3000, 7304.23.6030, 7304.23.6045, 7304.23.6060, 8431.43.8040 and may also enter under 8431.43.8060, 8431.43.4000, 7304.39.0028, 7304.39.0032, 7304.39.0036, 7304.39.0040, 7304.39.0044, 7304.39.0048, 7304.39.0052, 7304.39.0056, 7304.49.0015, 7304.49.0060, 7304.59.8020, 7304.59.8025, 7304.59.8030, 7304.59.8035, 7304.59.8040, 7304.59.8045, 7304.59.8050, and 7304.59.8055. Although the HTSUS subheadings are provided for convenience and customs purposes, the written product description remains dispositive.

A full description of the scope of the order is contained in the memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations to Ronald K. Lorentzen, Acting Assistant Secretary for Enforcement and Compliance, “Decision Memorandum for Preliminary Results of Countervailing Duty Administrative Review: Drill Pipe from the People’s Republic of China” (Preliminary Decision Memorandum), dated concurrently with this notice, and hereby adopted by this notice.

The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance’s Antidumping and Countervailing Duty Centralized Electronic Service System (IA ACCESS). IA ACCESS is available to registered users at <http://iaaccess.trade.gov> and in the Central Records Unit, room 7046 of the main Department of Commerce

⁵ See *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties*, 76 FR 65694 (October 24, 2011) (“*Assessment Practice Refinement*”); see also the “Assessment” section of this notice, below.

⁶ See *Assessment Practice Refinement*, 76 FR 65694.

⁷ *Id.*, 76 FR at 65694.

building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <http://enforcement.trade.gov/frn/index.html>. The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content. A list of topics discussed in the Preliminary Decision Memorandum is provided in the Appendix to this notice.

Methodology

The Department conducted this review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For the program found countervailable, we preliminarily determine that there is a subsidy, *i.e.*, a government-provided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific. *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

In making the preliminary findings, we relied, in part, on facts available and, because the Government of the PRC did not act to the best of its ability to respond to the Department's requests for information, we applied an adverse inference in selecting from among the facts otherwise available. *See* sections 776(a) and (b) of the Act. For further information, see "Use of Facts Otherwise Available and Adverse Inferences" in the Preliminary Decision Memorandum.

For a full description of the methodology underlying the Department's conclusions, *see* Preliminary Decision Memorandum.

Preliminary Results of the Review

As a result of this review, we preliminarily determine a net countervailable subsidy rate of 3.57 percent *ad valorem* for Shanxi Yida Special Steel Imp. & Exp. Co., Ltd. and its cross-owned affiliates Shanxi Yida Special Steel Group Co., Ltd. and Shanxi Yida Petroleum Equipment Manufacturing Co., Ltd. (collectively, the Yida Group), for the period January 1, 2013, through December 31, 2013.

Disclosure and Public Comment

The Department intends to disclose to parties to this proceeding the calculations performed in reaching the preliminary results within five days of the date of publication of these preliminary results.¹ Interested parties may submit written arguments (case briefs) within 30 days of publication of

the preliminary results and rebuttal comments (rebuttal briefs) within five days after the time limit for filing the case briefs.² Pursuant to 19 CFR 351.309(d)(2), rebuttal briefs must be limited to issues raised in the case briefs. Parties who submit arguments are requested to submit with the argument: (1) Statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Interested parties, who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce within 30 days after the date of publication of this notice.³ Requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues to be discussed. If a request for a hearing is made, we will inform parties of the scheduled date for the hearing, which will be held at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, at a time and location to be determined.⁴ Parties should confirm by telephone the date, time, and location of the hearing.

Parties are reminded that briefs and hearing requests are to be filed electronically using IA ACCESS and that electronically filed documents must be received successfully in their entirety by 5:00PM Eastern Time on the due date.

Unless the deadline is extended pursuant to section 751(a)(3)(A) of the Act, the Department will issue the final results of this administrative review, including the results of our analysis of the issues raised by parties in their comments, within 120 days after issuance of these preliminary results.

Assessment Rates

Consistent with section 751(a)(1) of the Act and 19 CFR 351.212(b)(2), upon issuance of the final results, the Department shall determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review. We intend to issue instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

Also in accordance with section 751(a)(1) of the Act, the Department intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amount shown above for

the reviewed company should the final results remain the same as these preliminary results. For all non-reviewed firms, we will instruct CBP to collect cash deposits of estimated countervailing duties at the most recent company-specific or all-others rate applicable to the company. These cash deposit requirements, when imposed, shall remain in effect until further notice.

These preliminary results of administrative review and notice are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213 and 351.221(b)(4).

Dated: November 4, 2014.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix: List of Topics Discussed in the Preliminary Decision Memorandum

1. Summary
2. Background
3. Scope of the Order
4. Subsidy Valuation Information
5. Loan Benchmark Rates
6. Use of Facts Otherwise Available and Adverse Inferences
7. Analysis of Programs
 - A. Program Preliminarily Determined To Be Countervailable
 - Provision of Electricity for Less Than Adequate Remuneration (LTAR)
 - B. Program Preliminarily Determined To Not Provide Benefits During the POR
 - Central and Provincial Policy Lending to Chinese Drill Pipe Producers
 - C. Programs Preliminarily Determined Not To Be Used
 - Export Loans From Policy Banks and State-Owned Commercial Banks
 - Treasury Bond Loans
 - Preferential Loans for State Owned Enterprises (SOEs)
 - Preferential Loans for Key Projects and Technologies
 - Preferential Lending To Drill Pipe Producers and Exporters Classified as Honorable Enterprises
 - Debt-to-Equity (D/E) Swaps
 - Loans and Interest Forgiveness for SOEs
 - Two Free, Three Half Tax Exemption for Foreign Invested Enterprises (FIEs) Exemption From City Construction Tax and Education Tax for FIEs
 - Local Income Tax Exemption and Reduction Programs for Productive FIEs Income Tax Reductions for Export-Oriented FIEs
 - Preferential Tax Programs for FIEs Recognized as High or New Technology Enterprises
 - Reduction In or Exemption From Fixed Assets Investment Orientation Regulatory Tax
 - Deed Tax Exemption for SOEs Undergoing Mergers or Restructuring
 - Income Tax Credits for Domestically-Owned Companies Purchasing Domestically-Produced Equipment

¹ See 19 CFR 351.224(b).

² See 19 CFR 351.309(c)(1)(ii) and 351.309(d)(1).

³ See 19 CFR 351.310(c).

⁴ See 19 CFR 351.310.

- Import Tariff and Value-Added Tax (VAT) Exemptions for FIEs and Certain Domestic Enterprises Using Imported Equipment in Encouraged Industries
- Export Incentive Payments Characterized as “VAT Rebates”
- VAT Rebates to Welfare Enterprises
- Provision of Green Tubes for LTAR
- Provision of Steel Rounds for LTAR
- Provision of Hot-Rolled Steel for LTAR
- Provision of Coking Coal for LTAR
- Provision of Land-Use Rights Within Designated Geographical Areas for LTAR
- Provision of Land to SOEs for LTAR
- Provision of Electricity at LTAR To Drill Pipe Producers Located in Jiangsu Province
- Provision of Water at LTAR To Drill Pipe Producers Located in Jiangsu Province
- Technology To Improve Trade R&D Fund
- Outstanding Growth Private Enterprise and Small and Medium-Sized Enterprises
- Development in Jiangyin Fund
- GOC and Sub-Central Government Grants, Loans, and Other Incentives for Development of Famous Brands and China World Top Brands
- Scientific Innovation Award
- Development Fund Grant
- State Key Technology Project Fund
- Export Assistance Grants
- Programs To Rebate Antidumping Legal Fees
- Grants and Tax Benefits to Loss-Making SOEs at National and Local Level
- Subsidies Provided To Drill Pipe Producers Located in Economic and Technological Development Zones (ETDZs) in Tianjin Binhai New Area
- Subsidies Provided To Drill Pipe Producers Located in ETDZs in Tianjin Economic and Technological Development Areas
- Subsidies Provided To Drill Pipe Producers Located in High-Tech Industrial Development Zones

8. Conclusion

[FR Doc. 2014–26787 Filed 11–12–14; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–580–877, C–489–823]

Welded Line Pipe From the Republic of Korea and the Republic of Turkey: Initiation of Countervailing Duty Investigations

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* November 13, 2014.

FOR FURTHER INFORMATION CONTACT:

Rebecca Trainor at (202) 482–4007 or Reza Karamloo at (202) 482–4470 (Republic of Korea); Elizabeth Eastwood at (202) 482–3874 or Dennis McClure at (202) 482–5973 (Republic of Turkey),

AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

The Petitions

On October 16, 2014, the Department of Commerce (the Department) received countervailing duty (CVD) petitions concerning imports of welded line pipe from the Republic of Korea (Korea) and the Republic of Turkey (Turkey) filed in proper form on behalf of American Cast Iron Pipe Company, Energex (a division of JMC Steel Group), Maverick Tube Corporation, Northwest Pipe Company, Stupp Corporation (a division of Stupp Bros., Inc.), Tex-Tube Company, TMK IPSCO, and Welspun Tubular LLC USA (collectively, the petitioners). The CVD petitions were accompanied by two antidumping duty (AD) petitions.¹ The petitioners are domestic producers of welded line pipe.²

On October 21, 2014, the Department requested information and clarification for certain areas of the Petitions.³ The petitioners filed responses to these requests on October 24, 2014, and October 29, 2014.⁴ On October 27 and October 31, 2014, we received submissions from United States Steel Corporation (U.S. Steel), a domestic producer of welded line pipe, in support of the Petitions.

In accordance with section 702(b)(1) of the Tariff Act of 1930, as amended (the Act), the petitioners allege that the

Government of Korea (GOK) and the Government of Turkey (GOT) are providing countervailable subsidies (within the meaning of sections 701 and 771(5) of the Act) to imports of welded line pipe from Korea and Turkey, respectively, and that such imports are materially injuring, or threatening material injury to, an industry in the United States. Also, consistent with section 702(b)(1) of the Act, the Petitions are accompanied by information reasonably available to the petitioners supporting their allegations.

The Department finds that the petitioners filed the Petitions on behalf of the domestic industry because the petitioners are interested parties as defined in section 771(9)(C) of the Act. The Department also finds that the petitioners demonstrated sufficient industry support with respect to the initiation of the CVD investigations that the petitioners are requesting.⁵

Periods of Investigation

The period of the investigation for both Korea and Turkey is January 1, 2013, through December 31, 2013.

Scope of the Investigations

The product covered by these investigations is welded line pipe from Korea and Turkey. For a full description of the scope of these investigations, see the “Scope of the Investigations” in Appendix I of this notice.

Comments on Scope of the Investigations

During our review of the Petitions, the Department issued questions to, and received responses from, the petitioners pertaining to the proposed scope to ensure that the scope language in the Petitions would be an accurate reflection of the products for which the domestic industry is seeking relief.⁶

As discussed in the preamble to the Department’s regulations,⁷ we are setting aside a period for interested parties to raise issues regarding product coverage (scope). The period for scope comments is intended to provide the Department with ample opportunity to consider all comments and to consult with parties prior to the issuance of the preliminary determination. If scope comments include factual information (see 19 CFR 351.102(b)(21)), all such factual information should be limited to public information. All such comments must be filed by 5:00 p.m. Eastern

⁵ See the “Determination of Industry Support for the Petitions” section below.

⁶ See General Issues Supplemental Questionnaire; see also General Issues Supplement.

⁷ See *Antidumping Duties; Countervailing Duties; Final rule*, 62 FR 27296, 27323 (May 19, 1997).

¹ See Petitions for the Imposition of Antidumping and Countervailing Duties: Welded API Line Pipe from South Korea and Turkey, dated October 16, 2014 (the Petitions).

² See Volume I of the Petitions, at 2–3.

³ See Letter from the Department to the petitioners entitled “Re: Petitions for the Imposition of Antidumping and Countervailing Duties on Imports of Welded Line Pipe from the Republic of Korea and the Republic of Turkey: Supplemental Questions,” dated October 21, 2014 (General Issues Supplemental Questionnaire), Letter from the Department to the petitioners entitled “Re: Petition for the Imposition of Countervailing Duties on Imports of Welded Line Pipe from the Republic of Turkey: Supplemental Questions,” dated October 21, 2014, and Letter from the Department to the petitioners entitled “Re: Petition for the Imposition of Countervailing Duties on Imports of Welded Line Pipe from the Republic of Turkey: Supplemental Questions,” dated October 21, 2014.

⁴ See “Welded API Line Pipe from Korea and Turkey: Response to Supplemental Questions,” dated October 24, 2014 (General Issues Supplement), “Welded Line Pipe from the Republic of Korea: Response to the Department’s Supplemental Questions,” dated October 24, 2014, “Welded API Line Pipe from Turkey: Response to Supplemental Questions,” dated October 24, 2014, and “Welded API Line Pipe from Korea and Turkey: Submission of CSI Letter of Support with 2013 Production and Revised Scope Language,” dated October 29, 2014 (Second General Issues Supplement).

Standard Time (EST) on November 25, 2014, which is 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information, must be filed by 5:00 p.m. EST on December 5, 2014, which is 10 calendar days after the initial comments.

The Department requests that any factual information the parties consider relevant to the scope of the investigations be submitted during this time period. However, if a party subsequently finds that additional factual information pertaining to the scope of the investigations may be relevant, the party may contact the Department and request permission to submit the additional information. All such comments must be filed on the records of the Korea and Turkey AD and CVD investigations.

Filing Requirements

All submissions to the Department must be filed electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (IA ACCESS).⁸ An electronically-filed document must be received successfully in its entirety by the time and date it is due. Documents excepted from the electronic submission requirements must be filed manually (*i.e.*, in paper form) with Enforcement and Compliance's APO/Dockets Unit, Room 1870, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, and stamped with the date and time of receipt by the applicable deadlines.

Consultations

Pursuant to section 702(b)(4)(A)(i) of the Act, the Department notified representatives of the GOK and the GOT of the receipt of the Petitions. Also, in accordance with section 702(b)(4)(A)(ii) of the Act, the Department provided representatives of the GOK and the GOT the opportunity for consultations with respect to the Petitions.⁹ Consultations were held separately with the GOK and GOT on November 4, 2014.¹⁰ All

memoranda are on file electronically via IA ACCESS.¹¹

Determination of Industry Support for the Petitions

Section 702(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 702(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) At least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 702(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, the Department shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the "industry."

Section 771(4)(A) of the Act defines the "industry" as the producers as a whole of a domestic like product, or those producers whose collective output of a domestic like product constitutes a major proportion of the total domestic production of the product. Thus, to determine whether a petition has the requisite industry support, the statute directs the Department to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether "the domestic industry" has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both the Department and the ITC must apply the same statutory definition regarding the domestic like product,¹² they do so for different purposes and pursuant to a separate and distinct authority. In addition, the Department's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not

render the decision of either agency contrary to law.¹³

Section 771(10) of the Act defines the domestic like product as "a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title." Thus, the reference point from which the domestic like product analysis begins is "the article subject to an investigation" (*i.e.*, the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition).

With regard to the domestic like product, the petitioners do not offer a definition of the domestic like product distinct from the scope of the investigations. Based on our analysis of the information submitted on the record, we have determined that welded line pipe, as defined in the scope of the investigations, constitutes a single domestic like product and we have analyzed industry support in terms of that domestic like product.¹⁴

In determining whether the petitioners have standing under section 702(c)(4)(A) of the Act, we considered the industry support data contained in the Petitions with reference to the domestic like product as defined in the "Scope of the Investigations," in Appendix I of this notice. To establish industry support, the petitioners provided their production of the domestic like product in 2013, as well as the production of a company that supports the Petitions, and compared this to the total production of the domestic like product for the entire domestic industry.¹⁵

On October 27, 2014, we received a submission from U.S. Steel, a domestic producer of welded line pipe. In the submission, U.S. Steel states that it supports the AD and CVD petitions on welded line pipe from Korea and

¹³ See *USEC, Inc. v. United States*, 132 F. Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd. v. United States*, 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989)).

¹⁴ For a discussion of the domestic like product analysis in this case, see Countervailing Duty Investigation Initiation Checklist: Welded Line Pipe from the Republic of Korea (Korea CVD Initiation Checklist) at Attachment II, Analysis of Industry Support for the Antidumping and Countervailing Duty Petitions Covering Welded Line Pipe from the Republic of Korea and the Republic of Turkey (Attachment II); and Countervailing Duty Investigation Initiation Checklist: Welded Line Pipe from the Republic of Turkey (Turkey CVD Initiation Checklist), at Attachment II. These checklists are dated concurrently with this notice and are on file electronically via IA ACCESS. Access to documents filed via IA ACCESS is also available in the Central Records Unit, Room 7046 of the main Department of Commerce building.

¹⁵ See General Issues Supplement, at 3–5 and Exhibits 3 and 4; see also Second General Issues Supplement, at Attachment 1.

⁸ See *Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures*, 76 FR 39263 (July 6, 2011) for details of the Department's electronic filing requirements, which went into effect on August 5, 2011. Information on help using IA ACCESS can be found at <https://iaaccess.trade.gov/help.aspx> and a handbook can be found at <https://iaaccess.trade.gov/help/Handbook%20on%20Electronic%20Filing%20Procedures.pdf>.

⁹ See Letters of invitation from the Department to the GOK and the GOT, both dated October 17, 2014.

¹⁰ See Memorandum to the File, "Consultations with Officials from the Government of the Republic of Korea Regarding the Countervailing Duty Petition Concerning Welded Line Pipe," dated November 5,

2014; see also Memorandum to the File, "Consultations with Officials from the Government of the Republic of Turkey Regarding the Countervailing Duty Petition Concerning Welded Line Pipe," dated November 4, 2014.

¹¹ See *supra* note 8 for information pertaining to IA ACCESS.

¹² See section 771(10) of the Act.

Turkey.¹⁶ In an additional submission on October 31, 2014, U.S. Steel provided its 2013 production of the domestic like product.¹⁷

We have relied upon data that the petitioners and U.S. Steel provided for purposes of measuring industry support.¹⁸

Based on information provided in the Petitions, supplemental submissions, and other information readily available to the Department, we determine that the petitioners have met the statutory criteria for industry support under section 702(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the Petitions account for at least 25 percent of the total production of the domestic like product.¹⁹ Based on information provided in the Petitions, supplemental submissions, and submissions from U.S. Steel, the domestic producers (or workers) have met the statutory criteria for industry support under section 702(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the Petitions account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petitions. Accordingly, the Department determines that the Petitions were filed on behalf of the domestic industry within the meaning of section 702(b)(1) of the Act.²⁰

The Department finds that the petitioners filed the Petitions on behalf of the domestic industry because they are interested parties as defined in section 771(9)(C) of the Act and they have demonstrated sufficient industry support with respect to the CVD investigations that they are requesting the Department initiate.²¹

Injury Test

Because Korea and Turkey are "Subsidies Agreement Countries" within the meaning of section 701(b) of the Act, section 701(a)(2) of the Act applies to these investigations. Accordingly, the ITC must determine whether imports of the subject merchandise from Korea and Turkey materially injure, or threaten material injury to, a U.S. industry.

Allegations and Evidence of Material Injury and Causation

The petitioners allege that imports of the subject merchandise are benefitting from countervailable subsidies and that such imports are causing, or threaten to cause, material injury to the U.S. industry producing the domestic like product. In addition, the petitioners allege that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.²²

The petitioners contend that the industry's injured condition is illustrated by reduced market share, underselling and price depression or suppression, lost sales and revenues, declining shipments, reduced production capacity, and a decline in financial performance.²³ We assessed the allegations and supporting evidence regarding material injury, threat of material injury, and causation, and we determined that these allegations are properly supported by adequate evidence and meet the statutory requirements for initiation.²⁴

Initiation of Countervailing Duty Investigations

Section 702(b)(1) of the Act requires the Department to initiate a CVD investigation whenever an interested party files a CVD petition on behalf of an industry that: (1) Alleges the elements necessary for an imposition of a duty under section 701(a) of the Act; and (2) is accompanied by information reasonably available to the petitioner supporting the allegations.

In the Petitions, the petitioners allege that producers/exporters of welded line pipe in Korea and Turkey benefited from countervailable subsidies bestowed by the governments of these countries, respectively. The Department has examined the Petitions and finds that they comply with the requirements of section 702(b)(1) of the Act. Therefore, in accordance with section 702(b)(1) of the Act, we are initiating CVD investigations to determine whether manufacturers, producers, or exporters of welded line pipe from Korea and Turkey receive countervailable subsidies from the

governments of these countries, respectively.

Korea

Based on our review of the Petition, we find that there is sufficient information to initiate a CVD investigation of 22 of the 23 alleged programs. For a full discussion of the basis for our decision to initiate or not initiate on each program, see Korea CVD Initiation Checklist.

Turkey

Based on our review of the Petition, we find that there is sufficient information to initiate a CVD investigation of 16 of the 18 alleged programs. For a full discussion of the basis for our decision to initiate or not initiate on each program, see Turkey CVD Initiation Checklist.

A public version of the initiation checklist for each investigation is available on IA ACCESS and at <http://trade.gov/enforcement/news.asp>.

In accordance with section 703(b)(1) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determinations no later than 65 days after the date of this initiation.

Respondent Selection

The petitioners named 13 companies as producers/exporters of welded line pipe from Korea and 13 companies as producers/exporters of welded line pipe from Turkey.²⁵ Following standard practice in CVD investigations, the Department will, where appropriate, select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports of welded line pipe during the period of investigation under the following Harmonized Tariff Schedule of the United States (HTSUS) numbers: 7305.11.10.30, 7305.11.50.00, 7305.12.10.30, 7305.12.50.00, 7305.19.10.30, 7306.19.10.10, 7306.19.10.50, 7306.19.51.10, and 7306.19.51.50. We intend to release CBP data under Administrative Protective Order (APO) to all parties with access to information protected by APO shortly after the announcement of these case initiations. The Department invites comments regarding CBP data and respondent selection within five calendar days of publication of this **Federal Register** notice. Comments must be filed electronically using IA ACCESS. An electronically-filed document must be received successfully in its entirety by the Department's electronic records system, IA ACCESS, by 5 p.m. Eastern time by the date noted

¹⁶ See Letter from U.S. Steel, dated October 27, 2014, at 1–2.

¹⁷ See Letter from U.S. Steel to the Department entitled "Re: Welded Line Pipe from the Republic of Korea and the Republic of Turkey," dated October 31, 2014.

¹⁸ See Korea CVD Initiation Checklist and Turkey CVD Initiation Checklist, at Attachment II.

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*

²² See General Issues Supplement, at 6 and Exhibit 7.

²³ See Volume I of the Petitions, at 14–18, 21–27, and Exhibits I–2, I–6, and I–8 through I–10; see also General Issues Supplement, at 6–7 and Exhibits 7 and 8.

²⁴ See Korea CVD Initiation Checklist and Turkey CVD Initiation Checklist, at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping and Countervailing Duty Petitions Covering Welded Line Pipe from the Republic of Korea and the Republic of Turkey.

²⁵ See Volume I of the Petitions, at Exhibit I–4.

above. We intend to make our decision regarding respondent selection within 20 days of publication of this **Federal Register** notice. Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305(b). Instructions for filing such applications may be found on the Department's Web site at <http://enforcement.trade.gov/apo>.

Distribution of Copies of the Petitions

In accordance with section 702(b)(4)(A)(i) of the Act and 19 CFR 351.202(f), copies of the public version of the Petitions have been provided to the GOK and GOT via IA ACCESS. Because of the particularly large number of producers/exporters identified in the Petitions, the Department considers the service of the public version of the Petitions to the foreign producers/exporters to be satisfied by the provision of the public version of the Petitions to the GOK and GOT, consistent with 19 CFR 351.203(c)(2).

ITC Notification

We have notified the ITC of our initiation, as required by section 702(d) of the Act.

Preliminary Determinations by the ITC

The ITC will preliminarily determine, within 45 days after the date on which the Petitions were filed, whether there is a reasonable indication that imports of welded line pipe from Korea and/or Turkey are materially injuring, or threatening material injury to, a U.S. industry.²⁶ A negative ITC determination for either country will result in the investigation being terminated with respect to that country;²⁷ otherwise, these investigations will proceed according to statutory and regulatory time limits.

Submission of Factual Information

On April 10, 2013, the Department published *Definition of Factual Information and Time Limits for Submission of Factual Information: Final Rule*, 78 FR 21246 (April 10, 2013), which modified two regulations related to AD and CVD proceedings: the definition of factual information (19 CFR 351.102(b)(21)), and the time limits for the submission of factual information (19 CFR 351.301). The final rule identifies five categories of factual information in 19 CFR 351.102(b)(21), which are summarized as follows: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly

available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by the Department; and (v) evidence other than factual information described in (i)–(iv). The final rule requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct. The final rule also modified 19 CFR 351.301 so that, rather than providing general time limits, there are specific time limits based on the type of factual information being submitted. These modifications are effective for all proceeding segments initiated on or after May 10, 2013, and thus are applicable to these investigations. Interested parties should review the final rule, available at <http://enforcement.trade.gov/frn/2013/1304frn/2013-08227.txt>, prior to submitting factual information in these investigations.

Revised Extension of Time Limits Regulation

On September 20, 2013, the Department modified its regulation concerning the extension of time limits for submissions in AD and CVD proceedings.²⁸ The modification clarifies that parties may request an extension of time limits before a time limit established under Part 351 expires, or as otherwise specified by the Secretary. In general, an extension request will be considered untimely if it is filed after the time limit established under Part 351 expires. For submissions which are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. on the due date. Examples include, but are not limited to: (1) Case and rebuttal briefs, filed pursuant to 19 CFR 351.309; (2) factual information to value factors under 19 CFR 351.408(c), or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2), filed pursuant to 19 CFR 351.301(c)(3) and rebuttal, clarification and correction information filed pursuant to 19 CFR 351.301(c)(3)(iv); (3) comments concerning the selection of a surrogate country and surrogate values and rebuttal; (4) comments concerning CBP data; and (5) quantity and value

questionnaires. Under certain circumstances, the Department may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, the Department will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. This modification also requires that an extension request must be made in a separate, stand-alone submission, and clarifies the circumstances under which the Department will grant untimely-filed requests for the extension of time limits. These modifications are effective for all segments initiated on or after October 21, 2013. Interested parties should review *Extension of Time Limits: Final Rule*, available at <http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm>, prior to submitting factual information in these investigations.

Certification Requirements

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.²⁹ Parties are hereby reminded that revised certification requirements are in effect for company/government officials, as well as their representatives. Investigations initiated on the basis of petitions filed on or after August 16, 2013, and other segments of any AD or CVD proceedings initiated on or after August 16, 2013, should use the formats for the revised certifications provided at the end of the *Final Rule*.³⁰ The Department intends to reject factual submissions if the submitting party does not comply with the applicable revised certification requirements.

Notification to Interested Parties

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305. On January 22, 2008, the Department published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures*, 73 FR 3634 (January 22, 2008). Parties wishing to participate in these investigations should ensure that they meet the requirements of these

²⁹ See section 782(b) of the Act.

³⁰ See *Certification of Factual Information To Import Administration During Antidumping and Countervailing Duty Proceedings*, 78 FR 42678 (July 17, 2013) (*Final Rule*); see also frequently asked questions regarding the *Final Rule*, available at http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.

²⁶ See section 703(a) of the Act.

²⁷ *Id.*

²⁸ See *Extension of Time Limits: Final Rule*, 78 FR 57790 (September 20, 2013).

procedures (e.g., the filing of letters of appearance as discussed at 19 CFR 351.103(d)).

This notice is issued and published pursuant to sections 702 and 777(i) of the Act.

Dated: November 5, 2014.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigations

The merchandise covered by these investigations is circular welded carbon and alloy steel (other than stainless steel) pipe of a kind used for oil or gas pipelines (welded line pipe), not more than 24 inches in nominal outside diameter, regardless of wall thickness, length, surface finish, end finish, or stenciling. Welded line pipe is normally produced to the American Petroleum Institute (API) specification 5L, but can be produced to comparable foreign specifications, to proprietary grades, or can be non-graded material. All pipe meeting the physical description set forth above, including multiple-stenciled pipe with an API or comparable foreign specification line pipe stencil is covered by the scope of these investigations.

The welded line pipe that is subject to these investigations is currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 7305.11.1030, 7305.11.5000, 7305.12.1030, 7305.12.5000, 7305.19.1030, 7305.19.5000, 7306.19.1010, 7306.19.1050, 7306.19.5110, and 7306.19.5150. The subject merchandise may also enter in HTSUS 7305.11.1060 and 7305.12.1060. While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of these investigations is dispositive.

[FR Doc. 2014-26897 Filed 11-12-14; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-941]

Certain Kitchen Appliance Shelving and Racks From the People's Republic of China: Final Results of Expedited First Sunset Review of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On August 1, 2014, the Department of Commerce (the "Department") published the notice of initiation of the first five-year ("sunset") review of the antidumping duty order on certain kitchen appliance shelving and racks ("KASR") from the People's Republic of China ("PRC") pursuant to section 751(c) of the Tariff Act of 1930,

as amended (the "Act").¹ As a result of this sunset review, the Department finds that revocation of the antidumping duty order on KASR from the PRC would be likely to lead to continuation or recurrence of dumping. The magnitude of the dumping margins likely to prevail is indicated in the "Final Results of Review" section of this notice.

DATES: *Effective Date:* November 13, 2014.

FOR FURTHER INFORMATION CONTACT:

Irene Gorelik, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482-6905.

SUPPLEMENTARY INFORMATION:

Background

As noted above, on August 1, 2014, the Department published the initiation of the first sunset review of KASR from the PRC.² On August 18, 2014, Nashville Wire Products, Inc. ("Nashville Wire") and SSW Holding Company, Inc. ("SSW") (collectively, "Petitioners") timely notified the Department of their intent to participate within the deadline specified in 19 CFR 351.218(d)(1)(i), claiming domestic interested party status under section 771(9)(C) of the Act.³ On September 2, 2014, the Department received an adequate substantive response from Petitioners within the deadline specified in 19 CFR 351.218(d)(3)(i).⁴ We received no responses from respondent interested parties. As a result, the Department conducted an expedited (120-day) sunset review of the order, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2).

Scope of the Order

The scope of the order consists of shelving and racks for refrigerators, freezers, combined refrigerator-freezers, other refrigerating or freezing equipment, cooking stoves, ranges, and ovens ("certain kitchen appliance shelving and racks" or "the merchandise under order").

The merchandise subject to the order is currently classifiable in the Harmonized Tariff Schedule of the United States ("HTSUS") statistical reporting numbers 8418.99.8050, 8418.99.8060, 7321.90.5000, 7321.90.6090, 8516.90.8000 and

8419.90.9520. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.⁵

Analysis of Comments Received

All issues raised in this sunset review are addressed in the Issues and Decision Memorandum. The issues discussed in the Issues and Decision Memorandum include the likelihood of continuation or recurrence of dumping and the magnitude of the margins likely to prevail if the order were to be revoked. Parties may find a complete discussion of all issues raised in the review and the corresponding recommendations in this public memorandum which is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System ("IA ACCESS"). IA ACCESS is available to registered users at <http://iaaccess.trade.gov>, and is available to all parties in the Central Records Unit, room 7046 of the main Department of Commerce building. In addition, a complete version of the Decision Memorandum can be accessed directly on the Internet at <http://enforcement.trade.gov/frn/index.html>. The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Final Results of Review

Pursuant to section 752(c) of the Act, the Department determines that revocation of the order would be likely to lead to continuation or recurrence of dumping at weighted-average margins up to 95.99 percent.

Administrative Protective Order

This notice also serves as the only reminder to parties subject to administrative protective order ("APO") of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return of destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an

⁵ For the full scope of the Order, see "Issues and Decision Memorandum for the Expedited First Sunset Review of the Antidumping Duty Order on Certain Kitchen Appliance Shelving and Racks from the People's Republic of China" from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Ronald K. Lorentzen, Acting Assistant Secretary for Enforcement and Compliance, dated concurrently with, and hereby adopted by, this notice ("Issues and Decision Memorandum").

¹ See *Initiation of Five-Year ("Sunset") Review*, 79 FR 44743 (August 1, 2014).

² *Id.*

³ See Petitioners' August 18, 2014, submission.

⁴ See Petitioners' September 2, 2014, submission.

APO is a violation which is subject to sanction.

We are publishing these final results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act.

Dated: November 4, 2014.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2014-26789 Filed 11-12-14; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-570-991]

Chlorinated Isocyanurates From the People's Republic of China: Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: Based on affirmative final determinations by the Department of Commerce ("Department") and the International Trade Commission ("ITC"), the Department is issuing a countervailing duty order on chlorinated isocyanurates ("Isos") from the People's Republic of China ("PRC").
DATES: *Effective Date:* November 13, 2014.

FOR FURTHER INFORMATION CONTACT: Paul Walker or Matthew Renkey, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482-0413 or (202) 482-2312, respectively.

Background

In accordance with section 705(d) of the Tariff Act of 1930, as amended ("Act"), on September 22, 2014, the Department published its final determination that countervailable subsidies are being provided to producers and exporters of Isos from the PRC. See *Chlorinated Isocyanurates from the People's Republic of China: Final Affirmative Countervailing Duty Determination*; 2012, 79 FR 56560 (September 22, 2014) ("Final Determination").

On November 3, 2014, the ITC notified the Department of its final determination pursuant to section 705(d) of the Act that an industry in the United States is threatened with material injury within the meaning of section 705(b)(1)(A)(ii) of the Act by reason of subsidized imports of subject merchandise from the PRC. See

Chlorinated Isocyanurates from China and Japan, USITC Investigation Nos. 701-TA-501 and 731-TA-1226 (Final), USITC Publication 4494 (November 2014).

Scope of the Order

The products covered by this order are chlorinated isocyanurates. Chlorinated isocyanurates are derivatives of cyanuric acid, described as chlorinated s-triazine triones. There are three primary chemical compositions of chlorinated isocyanurates: (1) Trichloroisocyanuric acid ("TCCA") (Cl₃(NCO)₃), (2) sodium dichloroisocyanurate (dihydrate) (NaCl₂(NCO)₃ X 2H₂O), and (3) sodium dichloroisocyanurate (anhydrous) (NaCl₂(NCO)₃). Chlorinated isocyanurates are available in powder, granular and solid (*e.g.*, tablet or stick) forms.

Chlorinated isocyanurates are currently classifiable under subheadings 2933.69.6015, 2933.69.6021, 2933.69.6050, 3808.50.4000, 3808.94.5000, and 3808.99.9500 of the Harmonized Tariff Schedule of the United States ("HTSUS"). The tariff classification 2933.69.6015 covers sodium dichloroisocyanurates (anhydrous and dihydrate forms) and trichloroisocyanuric acid. The tariff classifications 2933.69.6021 and 2933.69.6050 represent basket categories that include chlorinated isocyanurates and other compounds including an unfused triazine ring. The tariff classifications 3808.50.4000, 3808.94.5000 and 3808.99.9500 cover disinfectants that include chlorinated isocyanurates. The HTSUS subheadings are provided for convenience and customs purposes. The written description of the scope of this order is dispositive.

Countervailing Duty Order

In accordance with sections 705(b)(1)(A)(ii) and 705(d) of the Act, the ITC has notified the Department of its final determination that the industry in the United States producing Isos is threatened with material injury by reason of subsidized imports of drawn sinks from the PRC. Therefore, in accordance with section 705(c)(2) of the Act, we are publishing this countervailing duty order.

According to section 706(b)(2) of the Act, countervailing duties shall be assessed on subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the ITC's notice of final determination if that determination is based upon the threat of material injury. Section 706(b)(1) of the Act states, "{i}f

the Commission, in its final determination under section 705(b), finds material injury or threat of material injury which, but for the suspension of liquidation under section 703(d)(2), would have led to a finding of material injury, then entries of the merchandise subject to the countervailing duty order, the liquidation of which has been suspended under section 703(d)(2), shall be subject to the imposition of countervailing duties under section 701(a)." In addition, section 706(b)(2) of the Act requires U.S. Customs and Border Protection ("CBP") to refund any cash deposits or bonds of estimated countervailing duties posted before the date of publication of the ITC's final affirmative determination, if the ITC's final determination is based on threat other than the threat described in section 706(b)(1) of the Act. Because the ITC's final determination in this case is based on the threat of material injury and is not accompanied by a finding that injury would have resulted but for the imposition of suspension of liquidation of entries since the publication of the Department's *Preliminary Determination* in the **Federal Register**,¹ section 706(b)(2) of the Act applies.

Suspension of Liquidation

As a result of the ITC's determination and in accordance with section 706(a)(1) of the Act, the Department will direct CBP to assess, upon further instruction by the Department, countervailing duties equal to the amount of the net countervailable subsidy for all relevant entries of Isos from the PRC. The Department instructed CBP to discontinue the suspension of liquidation on June 24, 2014, in accordance with section 703(d) of the Act. Section 703(d) states that the suspension of liquidation pursuant to a preliminary determination may not remain in effect for more than four months. Entries of Isos from the PRC made on or after June 24, 2014, and prior to the date of publication of the ITC's final determination in the **Federal Register** are not liable for the assessment of countervailing duties because of the Department's discontinuation, effective June 24, 2014, of the suspension of liquidation.

In accordance with section 706 of the Act, the Department will direct CBP to reinstitute suspension of liquidation,

¹ See *Countervailing Duty Investigation of Chlorinated Isocyanurates from the People's Republic of China: Preliminary Determination and Alignment of Final Determination with Final Antidumping Determination*, 79 FR 10097 (February 24, 2014) ("Preliminary Determination").

effective on the date of publication of the ITC's notice of final determination in the **Federal Register**, and to require a cash deposit for each entry of subject merchandise in an amount equal to the net countervailable subsidy rates listed below. The all others rate applies to all producers and exporters of subject merchandise not specifically listed.

Company	Subsidy rate
Hebei Jiheng Chemicals Co., Ltd	20.06
Juancheng Kangtai Chemical Co., Ltd	1.55
All Others	10.81

Termination of the Suspension of Liquidation

The Department will instruct CBP to terminate the suspension of liquidation for entries of Isos from the PRC, entered or withdrawn from warehouse, for consumption prior to the publication of the ITC's notice of final determination. The Department will also instruct CBP to refund any cash deposits made and release any bonds with respect to entries of Isos entered, or withdrawn from warehouse, for consumption on or after February 24, 2014 (*i.e.*, the date of publication of the *Preliminary Determination*), but before June 24, 2014 (*i.e.*, the date suspension of liquidation was discontinued in accordance with section 703(d) of the Act).

This notice constitutes the countervailing duty order with respect to Isos from the PRC, pursuant to section 706(a) of the Act. Interested parties may contact the Department's Central Records Unit, Room 7046 of the main Commerce Building, for copies of an updated list of countervailing duty orders currently in effect.

This order is issued and published in accordance with section 706(a) of the Act and 19 CFR 351.211(b).

Dated: November 5, 2014.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2014-26795 Filed 11-12-14; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

Renewable Energy and Energy Efficiency Advisory Committee

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of an Open Meeting.

SUMMARY: The Renewable Energy and Energy Efficiency Advisory Committee (RE&EEAC) will hold a meeting on December 17, 2014. The meeting is open to the public and the room is disabled-accessible. Public seating is limited and available on a first-come, first-served basis.

DATES: December 17, 2014, from 9:00 a.m. to 4:00 p.m. Eastern Standard Time (EST). Members of the public wishing to attend the meeting must notify Andrew Bennett at the contact information below by 5:00 p.m. EST on Wednesday, December 10, in order to pre-register for clearance into the building. Please specify any requests for reasonable accommodation at least five business days in advance of the meeting. Last minute requests will be accepted, but may be impossible to fill.

ADDRESSES: The meeting will be held at the U.S. Department of Commerce, Room 6029, 1401 Constitution Avenue NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Andrew Bennett, Office of Energy and Environmental Industries (OEEI), International Trade Administration, U.S. Department of Commerce at (202) 482-5235; email: Andrew.Bennett@trade.gov. This meeting is physically accessible to people with disabilities. Requests for auxiliary aids should be directed to OEEI at (202) 482-5235.

SUPPLEMENTARY INFORMATION:

Background: The Secretary of Commerce established the RE&EEAC pursuant to his discretionary authority and in accordance with the Federal Advisory Committee Act (5 U.S.C. App.) on July 14, 2010. The RE&EEAC was re-chartered on June 12, 2014. The RE&EEAC provides the Secretary of Commerce with consensus advice from the private sector on the development and administration of programs and policies to enhance the international competitiveness of the U.S. renewable energy and energy efficiency industries.

During the December 17th meeting of the RE&EEAC, committee members will discuss key objectives and the types of issues they plan to address during the course of the Committee's two-year charter. Previous recommendations were developed by the previous Committee on finance, U.S. competitiveness, trade policy, and trade promotion.

A limited amount of time, from approximately 3:30 p.m. to 3:45 p.m., will be available for pertinent oral comments from members of the public attending the meeting. To accommodate as many speakers as possible, the time for public comments will be limited to five minutes per person. Individuals

wishing to reserve additional speaking time during the meeting must contact Mr. Bennett and submit a brief statement of the general nature of the comments, as well as the name and address of the proposed participant by 5:00 p.m. EST on Wednesday, December 10, 2014. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, the International Trade Administration may conduct a lottery to determine the speakers. Speakers are requested to bring at least 20 copies of their oral comments for distribution to the participants and the public at the meeting.

Any member of the public may submit pertinent written comments concerning the RE&EEAC's affairs at any time before or after the meeting. Comments may be submitted to the Renewable Energy and Energy Efficiency Advisory Committee, c/o: Andrew Bennett, Office of Energy and Environmental Industries, U.S. Department of Commerce, Mail Stop: 4053, 1401 Constitution Avenue NW., Washington, DC 20230. To be considered during the meeting, written comments must be received no later than 5:00 p.m. EST on Wednesday, December 10, 2014, to ensure transmission to the Committee prior to the meeting. Comments received after that date will be distributed to the members but may not be considered at the meeting.

Copies of RE&EEAC meeting minutes will be available within 30 days following the meeting.

Dated: November 6, 2014.

Catherine Vial,

Team Leader, Environmental Industries.

[FR Doc. 2014-26805 Filed 11-12-14; 8:45 am]

BILLING CODE 3510-DR-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; National Saltwater Angler Registry

AGENCY: National Oceanic and Atmospheric Administration, Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information

collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before January 12, 2015.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at Jjessup@doc.gov).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Gordon Colvin (240) 357-4524 or Gordon.Colvin@noaa.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for extension of a currently approved collection.

The National Saltwater Angler Registry Program (Registry Program) was established to implement recommendations included in the review of national saltwater angling data collection programs conducted by the National Research Council (NRC) in 2005/2006, and the provisions of the Magnuson-Stevens Reauthorization Act, codified at Section 401(g) of the Magnuson-Stevens Fishery Conservation and Management Act (MSA), which require the Secretary of Commerce to commence improvements to recreational fisheries surveys, including establishing a national saltwater angler and for-hire vessel registry, by January 1, 2009. A final rule that includes regulatory measures to implement the Registry Program (RIN 0648-AW10) was adopted and codified in 50 CFR 600.1400-600.1417.

The Registry Program collects identification and contact information from those anglers and for-hire vessels who are involved in recreational fishing in the United States Exclusive Economic Zone or for anadromous fish in any waters, unless the anglers or vessels are exempted from the registration requirement. The data that is collected includes: For anglers: Name, address, date of birth, telephone contact information and region(s) of the country in which they fish; for for-hire vessels: Owner and operator name, address, date of birth, telephone contact information, vessel name and registration/documentation number and home port or primary operating area. This information is compiled into a national and/or series of regional registries that is being used to support surveys of recreational anglers and for-hire vessels to develop estimates of recreational angling effort.

II. Method of Collection

Persons may register in two ways: Via a toll-free telephone number or on line at a NOAA-maintained Web site. Registration cards, valid for one year from the date of issuance, are mailed to registrants.

III. Data

OMB Control Number: 0648-0578.

Form Number(s): None.

Type of Review: Regular submission (extension of a currently approved collection).

Affected Public: Individuals or households; business or other for-profit organizations.

Estimated Number of Respondents: 25,916.

Estimated Time per Response: 3 minutes.

Estimated Total Annual Burden Hours: 1296.

Estimated Total Annual Cost to Public: \$0 in recordkeeping/reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: November 6, 2014.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2014-26786 Filed 11-12-14; 8:45 am]

BILLING CODE 3510-22-P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No: CFPB-2014-0030]

Agency Information Collection Activities: Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Consumer Financial Protection Bureau (Bureau) is proposing to renew the approval for an existing information collection, titled, "CFPB State Official Notification Rule."

DATES: Written comments are encouraged and must be received on or before January 12, 2015 to be assured of consideration.

ADDRESSES: You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

- Electronic: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Mail: Consumer Financial Protection Bureau (Attention: PRA Office), 1700 G Street NW., Washington, DC 20552.

- Hand Delivery/Courier: Consumer Financial Protection Bureau (Attention: PRA Office), 1275 First Street NE., Washington, DC 20002.

Please note that comments submitted after the comment period will not be accepted. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or social security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Documentation prepared in support of this information collection request is available at www.regulations.gov. Requests for additional information should be directed to the Consumer Financial Protection Bureau, (Attention: PRA Office), 1700 G Street NW., Washington, DC 20552, (202) 435-9575, or email: PRA@cfpb.gov. *Please do not submit comments to this mailbox.*

SUPPLEMENTARY INFORMATION:

Title of Collection: CFPB State Official Notification Rule.

OMB Control Number: 3170-0019.

Type of Review: Extension without change of a currently approved collection.

Affected Public: State governments, District of Columbia, and U.S. Territories.

Estimated Number of Respondents: 56.

Estimated Total Annual Burden Hours: 2.

Abstract: Section 1042 of the Dodd-Frank Wall Street Reform and Consumer Protection Act, 12 U.S.C. 5552 ("Act"), gave authority to certain State and U.S. territorial officials to enforce the Act

and regulations prescribed thereunder. Section 1042 also requires that the Bureau issue a rule establishing how states are to provide notice to the Bureau before taking action to enforce the Act (or, in emergency situations, immediately after taking such an action). In accordance with the requirements of the Act, the Bureau issued a final rule (12 CFR 1082.1) establishing that notice should be provided at least 10 days before the filing of an action, with certain exceptions, and setting forth a limited set of information which is to be provided with the notice.

OMB's approval for this collection of information is scheduled to expire on 04/30/2015. Pursuant to the requirements set forth in the PRA implementing regulations at 5 CFR 1320.12, *Clearance of collections of information in current rules*, this request is for OMB to extend (renew) its approval for this collection of information for an additional three years.

Request for Comments: Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record.

Dated: November 6, 2014.

Nellisha Ramdass,

Acting Chief Information Officer, Bureau of Consumer Financial Protection.

[FR Doc. 2014-26834 Filed 11-12-14; 8:45 am]

BILLING CODE 4810-AM-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC15-19-000.

Applicants: Seiling Wind, LLC, Seiling Wind II, LLC, Seiling Wind Interconnection Services, LLC, Palo Duro Wind Energy, LLC, Palo Duro Wind Interconnection Services.

Description: Application for Authorization Under Section 203 of the Federal Power Act and Request for Expedited Action of Seiling Wind, LLC, et al.

Filed Date: 10/31/14.

Accession Number: 20141031-5329.

Comments Due: 5 p.m. ET 11/21/14.

Docket Numbers: EC15-20-000.

Applicants: ALLETE Clean Energy, Inc.

Description: Joint Application Under Section 203 of the Federal Power Act of Storm Lake Power Partners and ALLETE Clean Energy, Inc.

Filed Date: 10/31/14.

Accession Number: 20141031-5332.

Comments Due: 5 p.m. ET 11/21/14.

Docket Numbers: EC15-21-000.

Applicants: Rising Tree Wind Farm LLC, Rising Tree Wind Farm II LLC.

Description: Application for Authorization for Disposition of Jurisdictional Facilities and Request for Expedited Action of Rising Tree Wind Farm LLC, et al.

Filed Date: 10/31/14.

Accession Number: 20141031-5339.

Comments Due: 5 p.m. ET 11/21/14.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11-4633-002.

Applicants: Madison Gas and Electric Company.

Description: Madison Gas & Electric Company submits a notice of non-material change in status regarding the joint venture and potential acquisition of interest in generation facilities.

Filed Date: 10/27/14.

Accession Number: 20141030-0001.

Comments Due: 5 p.m. ET 11/17/14.

Docket Numbers: ER14-2419-002.

Applicants: ISO New England Inc.

Description: Compliance filing per 35: Two-Settlement Market Design Compliance Filing to be effective 6/1/2018.

Filed Date: 11/3/14.

Accession Number: 20141103-5032.

Comments Due: 5 p.m. ET 11/24/14.

Docket Numbers: ER14-2708-002.

Applicants: Seiling Wind, LLC.

Description: Notice of Change in Status of Seiling Wind, LLC.

Filed Date: 10/31/14.

Accession Number: 20141031-5328.

Comments Due: 5 p.m. ET 11/21/14.

Docket Numbers: ER15-286-000.

Applicants: South Eastern Electric Development Corp.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): Revised Market Based Rate Tariff to be effective 11/1/2014.

Filed Date: 10/31/14.

Accession Number: 20141031-5251.

Comments Due: 5 p.m. ET 11/21/14.

Docket Numbers: ER15-287-000.

Applicants: South Eastern Generating Corp.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): Revised Market Based Rate Tariff to be effective 11/1/2014.

Filed Date: 10/31/14.

Accession Number: 20141031-5252.

Comments Due: 5 p.m. ET 11/21/14.

Docket Numbers: ER15-288-000.

Applicants: Utility Contract Funding II, L.L.C.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): Revised MBR Tariff to be effective 11/1/2014.

Filed Date: 10/31/14.

Accession Number: 20141031-5253.

Comments Due: 5 p.m. ET 11/21/14.

Docket Numbers: ER15-289-000.

Applicants: TAQA Gen X LLC.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): Revised MBR Tariff to be effective 11/1/2014.

Filed Date: 10/31/14.

Accession Number: 20141031-5254.

Comments Due: 5 p.m. ET 11/21/14.

Docket Numbers: ER15-290-000.

Applicants: NorthWestern Corporation.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): SA 605 Third Revised—NITSA with Bonneville Power Administration to be effective 1/1/2015.

Filed Date: 10/31/14.

Accession Number: 20141031-5255.

Comments Due: 5 p.m. ET 11/21/14.

Docket Numbers: ER15-291-000.

Applicants: California Independent System Operator Corporation.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2014-10-31 CopperMountain4_UFA to be effective 10/29/2014.

Filed Date: 10/31/14.

Accession Number: 20141031-5256.

Comments Due: 5 p.m. ET 11/21/14.

Docket Numbers: ER15-292-000.

Applicants: NaturEner Glacier Wind Energy 2, LLC.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): Market Based Rate Tariff to be effective 11/1/2014.

Filed Date: 10/31/14.

Accession Number: 20141031-5267.

Comments Due: 5 p.m. ET 11/21/14.

Docket Numbers: ER15-293-000.

Applicants: NaturEner Montana Wind Energy, LLC.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): Market Based Rate Tariff to be effective 11/1/2014.

Filed Date: 10/31/14.
Accession Number: 20141031–5268.
Comments Due: 5 p.m. ET 11/21/14.
Docket Numbers: ER15–294–000.
Applicants: Puget Sound Energy, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): Air Liquide NITSA SA No 693 to be effective 10/1/2014.
Filed Date: 10/31/14.
Accession Number: 20141031–5269.
Comments Due: 5 p.m. ET 11/21/14.
Docket Numbers: ER15–295–000.
Applicants: Black Hills/Colorado Electric Utility Company, LP.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): Joint Dispatch Transmission Service to be effective 1/1/2015.
Filed Date: 10/31/14.
Accession Number: 20141031–5270.
Comments Due: 5 p.m. ET 11/21/14.
Docket Numbers: ER15–296–000.
Applicants: Puget Sound Energy, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): BELM CS Orchard NITSA No 709 to be effective 10/1/2014.
Filed Date: 10/31/14.
Accession Number: 20141031–5271.
Comments Due: 5 p.m. ET 11/21/14.
Docket Numbers: ER15–297–000.
Applicants: LDVF1 TEP LLC.
Description: Initial rate filing per 35.12: Market Based Rate Filing to be effective 1/1/2015.
Filed Date: 10/31/14.
Accession Number: 20141031–5272.
Comments Due: 5 p.m. ET 11/21/14.
Docket Numbers: ER15–298–000.
Applicants: Puget Sound Energy, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): BELM CS Roeder NITSA SA No 706 to be effective 10/1/2014.
Filed Date: 10/31/14.
Accession Number: 20141031–5273.
Comments Due: 5 p.m. ET 11/21/14.
Docket Numbers: ER15–299–000.
Applicants: Puget Sound Energy, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): Boeing NITSA SA No 677 to be effective 10/1/2014.
Filed Date: 10/31/14.
Accession Number: 20141031–5274.
Comments Due: 5 p.m. ET 11/21/14.
Docket Numbers: ER15–300–000.
Applicants: Puget Sound Energy, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): Intel NITSA SA No 688 to be effective 10/1/2014.
Filed Date: 10/31/14.
Accession Number: 20141031–5276.
Comments Due: 5 p.m. ET 11/21/14.
Docket Numbers: ER15–301–000.
Applicants: Puget Sound Energy, Inc.
Description: Initial rate filing per 35.12: Port of Seattle NITSA SA No 484 to be effective 10/1/2014.
Filed Date: 10/31/14.

Accession Number: 20141031–5277.
Comments Due: 5 p.m. ET 11/21/14.
Docket Numbers: ER15–302–000.
Applicants: Puget Sound Energy, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): Tesoro NITSA SA No 703 to be effective 10/1/2014.
Filed Date: 10/31/14.
Accession Number: 20141031–5278.
Comments Due: 5 p.m. ET 11/21/14.
Docket Numbers: ER15–303–000.
Applicants: PJM Interconnection, L.L.C., American Transmission Systems, Incorporation.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): ATSI submits revisions to OATT Att H–21, H–21A and H–21B to be effective 1/1/2015.
Filed Date: 10/31/14.
Accession Number: 20141031–5279.
Comments Due: 5 p.m. ET 11/21/14.
Docket Numbers: ER15–304–000.
Applicants: Power Contract Financing II, L.L.C.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): Revised MBR Tariff to be effective 11/1/2014.
Filed Date: 10/31/14.
Accession Number: 20141031–5288.
Comments Due: 5 p.m. ET 11/21/14.
Docket Numbers: ER15–305–000.
Applicants: NaturEner Glacier Wind Energy 1, LLC.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): Market Based Rate Tariff to be effective 11/1/2014.
Filed Date: 10/31/14.
Accession Number: 20141031–5292.
Comments Due: 5 p.m. ET 11/21/14.
Docket Numbers: ER15–306–000.
Applicants: NaturEner Power Watch, LLC.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): MBR Tariff to be effective 11/1/2014.
Filed Date: 10/31/14.
Accession Number: 20141031–5294.
Comments Due: 5 p.m. ET 11/21/14.
Docket Numbers: ER15–307–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): Revisions to Attachment J—Section III to be effective 1/1/2015.
Filed Date: 10/31/14.
Accession Number: 20141031–5295.
Comments Due: 5 p.m. ET 11/21/14.
Docket Numbers: ER15–308–000.
Applicants: NaturEner Rim Rock Wind Energy, LLC.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): MBR Tariff to be effective 11/1/2014.
Filed Date: 10/31/14.
Accession Number: 20141031–5299.
Comments Due: 5 p.m. ET 11/21/14.
Docket Numbers: ER15–309–000.

Applicants: Idaho Power Company.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): Amended BPA USBR NITSA Jan 2015 Filing to be effective 12/31/9998.
Filed Date: 10/31/14.
Accession Number: 20141031–5305.
Comments Due: 5 p.m. ET 11/21/14.
Docket Numbers: ER15–310–000.
Applicants: Ameren Transmission Company of Illinois.
Description: Request for Approval of Updated Depreciation Accrual Rates of Ameren Transmission Company of Illinois.
Filed Date: 10/31/14.
Accession Number: 20141031–5331.
Comments Due: 5 p.m. ET 11/21/14.
Docket Numbers: ER15–311–000.
Applicants: PacifiCorp.
Description: Notice of Termination of PacifiCorp-SMUD Rate Schedule No. 250.
Filed Date: 10/31/14.
Accession Number: 20141031–5338.
Comments Due: 5 p.m. ET 11/21/14.
 The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.
 Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern Time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.
 eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 3, 2014.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014–26755 Filed 11–12–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP15–138–000.

Applicants: Great Lakes Gas Transmission Limited Par.
Description: § 4(d) rate filing per 154.204: T Rate Schedules—Volume No. 2 to be effective 11/1/2014.
Filed Date: 11/3/14.
Accession Number: 20141103–5029.
Comments Due: 5 p.m. ET 11/17/14.
Docket Numbers: RP15–139–000.
Applicants: ANR Pipeline Company.
Description: § 4(d) rate filing per 154.204: X-Rate Schedules Volume No. 2 to be effective 11/1/2014.
Filed Date: 11/3/14.
Accession Number: 20141103–5041.
Comments Due: 5 p.m. ET 11/17/14.
Docket Numbers: RP15–140–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) rate filing per 154.204: ConEd 11–1–2014 NJNY Dual Fuel Release to be effective 11/1/2014.
Filed Date: 11/3/14.
Accession Number: 20141103–5042.
Comments Due: 5 p.m. ET 11/17/14.
Docket Numbers: RP15–141–000.
Applicants: Kern River Gas Transmission Company.
Description: § 4(d) rate filing per 154.204: 2014 Correction to Miscellaneous to be effective 12/1/2014.
Filed Date: 11/3/14.
Accession Number: 20141103–5050.
Comments Due: 5 p.m. ET 11/17/14.
Docket Numbers: RP15–142–000.
Applicants: Rockies Express Pipeline LLC.
Description: § 4(d) rate filing per 154.204: Neg Rate 2014–11–3 Antero to be effective 11/1/2014.
Filed Date: 11/3/14.
Accession Number: 20141103–5070.
Comments Due: 5 p.m. ET 11/17/14.
Docket Numbers: RP15–143–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: § 4(d) rate filing per 154.204: Nov 2014 Re-releases of Ramapo Capacity to be effective 11/1/2014.
Filed Date: 11/3/14.
Accession Number: 20141103–5075.
Comments Due: 5 p.m. ET 11/17/14.
Docket Numbers: RP15–144–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) rate filing per 154.204: Cap Rel Neg Rate Agmt (Petrohawk 41448 to Texla 43360) to be effective 11/1/2014.
Filed Date: 11/3/14.
Accession Number: 20141103–5076.
Comments Due: 5 p.m. ET 11/17/14.
Docket Numbers: RP15–145–000.
Applicants: Southwestern Energy Services Company, Chesapeake Energy Marketing Inc..

Description: Joint Petition for Limited Waiver and Request for Expedited Action of Chesapeake Energy Marketing, Inc. and Southwestern Energy Services Company.

Filed Date: 11/3/14.

Accession Number: 20141103–5138.

Comments Due: 5 p.m. ET 11/13/14.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR § 385.211 and § 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP14–886–001.

Applicants: Equitrans, L.P.

Description: Compliance filing per 154.203: Compliance Filing—Offers to Purchase Capacity to be effective 10/16/2014.

Filed Date: 11/3/14.

Accession Number: 20141103–5096.

Comments Due: 5 p.m. ET 11/17/14.

Docket Numbers: RP14–887–001.

Applicants: Rager Mountain Storage Company LLC.

Description: Compliance filing per 154.203: Compliance Filing—Offers to Purchase Capacity to be effective 10/16/2014.

Filed Date: 11/3/14.

Accession Number: 20141103–5097.

Comments Due: 5 p.m. ET 11/17/14.

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR § 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 04, 2014.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014–26758 Filed 11–12–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–4315–003; ER10–3110–002; ER10–3144–003.

Applicants: Gila River Power LLC, Union Power Partners, L.P., Entegra Power Services LLC.

Description: Notice of Non-Material Change in Status of the Entegra Public Utilities.

Filed Date: 11/3/14.

Accession Number: 20141103–5121.

Comments Due: 5 p.m. ET 11/24/14.

Docket Numbers: ER14–355–000.

Applicants: Starttrans IO, LLC.

Description: eTariff filing per 35.19a(b): Refund Report to be effective N/A.

Filed Date: 11/3/14.

Accession Number: 20141103–5137.

Comments Due: 5 p.m. ET 11/24/14.

Docket Numbers: ER15–70–000.

Applicants: Erie Power, LLC.

Description: Supplement to October 9, 2014 Erie Power, LLC tariff filing.

Filed Date: 10/31/14.

Accession Number: 20141031–5344.

Comments Due: 5 p.m. ET 11/14/14.

Docket Numbers: ER15–312–000.

Applicants: Southwestern Electric Power Company.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): SWEPCO–ETEC NTEC PSA Amendment to be effective 1/1/2015.

Filed Date: 11/3/14.

Accession Number: 20141103–5054.

Comments Due: 5 p.m. ET 11/24/14.

Docket Numbers: ER15–313–000.

Applicants: DTE Electric Company.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): Village of Clinton Interconnection Agreement to be effective 11/28/2014.

Filed Date: 11/3/14.

Accession Number: 20141103–5119.

Comments Due: 5 p.m. ET 11/24/14.

Docket Numbers: ER15–314–000.

Applicants: NaturEner Wind Watch, LLC.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): Revised MBR Tariff to be effective 11/3/2014.

Filed Date: 11/3/14.

Accession Number: 20141103–5122.

Comments Due: 5 p.m. ET 11/24/14.

Docket Numbers: ER15–315–000.

Applicants: Starttrans IO, LLC.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2015 Update to TRBAA in Appendix I to be effective 1/1/2015.

Filed Date: 11/3/14.

Accession Number: 20141103–5148.

Comments Due: 5 p.m. ET 11/24/14.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 3, 2014.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014–26756 Filed 11–12–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG15–11–000.

Applicants: Duke Energy Beckjord Storage, LLC.

Description: Notice of Self-Certification as an Exempt Wholesale Generator of Duke Energy Beckjord Storage, LLC.

Filed Date: 11/3/14.

Accession Number: 20141103–5157.

Comments Due: 5 p.m. ET 11/24/14.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2983–004; ER10–2980–004; ER10–1777–005.

Applicants: Sundevil Power Holdings, LLC, Castleton Energy Services, LLC, Castleton Power, LLC.

Description: Second Supplement to July 1, 2013 Updated Market Power Analysis for the Southwest Region of the Wayzata Entities, et. al.

Filed Date: 10/31/14.

Accession Number: 20141031–5063.

Comments Due: 5 p.m. ET 11/21/14.

Docket Numbers: ER11–3391–003; ER11–4589–001; ER11–4591–001; ER10–

2400–004; ER11–4592–001; ER11–4593–001.

Applicants: Dempsey Ridge Wind Farm, LLC, EcoGrove Wind LLC, Red Hills Wind Project, L.L.C., Blue Canyon Windpower LLC, Tatanka Wind Power, LLC, Nevada Solar One, LLC.

Description: Notice of Non-Material Change in Status of AENAC Sellers.

Filed Date: 11/3/14.

Accession Number: 20141103–5192.

Comments Due: 5 p.m. ET 11/24/14.

Docket Numbers: ER13–80–004.

Applicants: Tampa Electric Company.

Description: Compliance filing per 35: OATT Order No. 1000 Compliance Filing 2014 to be effective 1/1/2015.

Filed Date: 11/4/14.

Accession Number: 20141104–5078.

Comments Due: 5 p.m. ET 11/25/14.

Docket Numbers: ER13–86–004.

Applicants: Duke Energy Florida, Inc., Duke Energy Carolinas, LLC.

Description: Compliance filing per 35: Order 1000 FRCC November 2014 Compliance Filing to be effective 1/1/2015.

Filed Date: 11/4/14.

Accession Number: 20141104–5051.

Comments Due: 5 p.m. ET 11/25/14.

Docket Numbers: ER15–230–000.

Applicants: GP Renewables & Trading, LLC.

Description: Supplement to October 29, 2014 GP Renewables & Trading, LLC tariff filing.

Filed Date: 11/3/14.

Accession Number: 20141103–5188.

Comments Due: 5 p.m. ET 11/19/14

Docket Numbers: ER15–316–000.

Applicants: Green Current Solutions, LLC.

Description: Tariff Withdrawal per 35.15: Green Current Solutions Cancellation to be effective 1/3/2015.

Filed Date: 11/3/14.

Accession Number: 20141103–5169.

Comments Due: 5 p.m. ET 11/24/14.

Docket Numbers: ER15–317–000.

Applicants: Utility Bid USA, LLC.

Description: Tariff Withdrawal per 35.15: Utility Bid USA, LLC Cancellation of Tariff to be effective 1/3/2015.

Filed Date: 11/3/14.

Accession Number: 20141103–5170.

Comments Due: 5 p.m. ET 11/24/14.

Docket Numbers: ER15–318–000.

Applicants: Platinum Energy, LLC.

Description: Tariff Withdrawal per 35.15: Platinum Energy, LLC Tariff Cancellation to be effective 1/3/2015.

Filed Date: 11/3/14.

Accession Number: 20141103–5171.

Comments Due: 5 p.m. ET 11/24/14.

Docket Numbers: ER15–319–000.

Applicants: Avista Corporation.

Description: Initial rate filing per 35.12 Avista Corp Service Agreement No. 545 to be effective 1/1/2015.

Filed Date: 11/4/14.

Accession Number: 20141104–5002.

Comments Due: 5 p.m. ET 11/25/14.

Docket Numbers: ER15–320–000.

Applicants: PJM Interconnection, L.L.C.

Description: \$ 205(d) rate filing per 35.13(a)(2)(iii): Ministerial Clean-Up Filing—Att K-Appx and OA Sched 1 as a result of ER14–623 to be effective 11/4/2014.

Filed Date: 11/4/14.

Accession Number: 20141104–5071.

Comments Due: 5 p.m. ET 11/25/14.

Docket Numbers: ER15–321–000.

Applicants: PJM Interconnection, L.L.C.

Description: \$ 205(d) rate filing per 35.13(a)(2)(iii): Ministerial Clean-Up Filing to correct Attachment DD.2 to be effective 11/4/2014.

Filed Date: 11/4/14

Accession Number: 20141104–5072

Comments Due: 5 p.m. ET 11/25/14

Docket Numbers: ER15–322–000.

Applicants: California Independent System Operator Corporation.

Description: \$ 205(d) rate filing per 35.13(a)(2)(iii): 2014-11-04 CDWR LGIAs to be effective 1/1/2015.

Filed Date: 11/4/14.

Accession Number: 20141104–5102.

Comments Due: 5 p.m. ET 11/25/14.

Docket Numbers: ER15–324–000.

Applicants: Public Service Company of Colorado.

Description: \$ 205(d) rate filing per 35.13(a)(2)(iii): PacifiCorp Exchange Agreement to be effective 1/1/2015.

Filed Date: 11/4/14.

Accession Number: 20141104–5119.

Comments Due: 5 p.m. ET 11/25/14.

Docket Numbers: ER15–325–000.

Applicants: ISO New England Inc. *Description:* ISO New England Inc. submits Installed Capacity Requirement, Hydro Quebec Interconnection Capability Credits and Related Values for the 2018/2019 Capacity Commitment Period.

Filed Date: 11/4/14.

Accession Number: 20141104–5129.

Comments Due: 5 p.m. ET 11/25/14.

Docket Numbers: ER15–326–000.

Applicants: Public Service Company of Colorado.

Description: \$ 205(d) rate filing per 35.13(a)(2)(iii): Joint Dispatch Agreement to be effective 1/1/2015.

Filed Date: 11/4/14.

Accession Number: 20141104–5133.

Comments Due: 5 p.m. ET 11/25/14.

Docket Numbers: ER15–327–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) rate filing per 35.13(a)(2)(iii); Service Agreement No. 3257; Queue No. W4-097 to be effective 10/28/2014.

Filed Date: 11/4/14.

Accession Number: 20141104-5145.

Comments Due: 5 p.m. ET 11/25/14.

Docket Numbers: ER15-328-000.

Applicants: ISO New England Inc.

Description: ISO New England Inc.

submits Informational Filing for Qualification in the Forward Capacity Market.

Filed Date: 11/4/14.

Accession Number: 20141104-5148.

Comments Due: 5 p.m. ET 11/19/14.

Docket Numbers: ER15-329-000.

Applicants: Golden Spread Electric Cooperative, Inc.

Description: § 205(d) rate filing per 35.13(a)(2)(iii); Greenbelt Amended SFA Filing to be effective 12/31/2014.

Filed Date: 11/4/14.

Accession Number: 20141104-5152.

Comments Due: 5 p.m. ET 11/25/14.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

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eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: November 04, 2014.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014-26757 Filed 11-12-14; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9919-19-OGC]

Proposed Settlement Agreement, Clean Air Act Citizen Suit

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed settlement agreement; request for public comment.

SUMMARY: In accordance with section 113(g) of the Clean Air Act, as amended

("CAA" or the "Act"), notice is hereby given of a proposed settlement agreement to address a lawsuit filed by Environmental Integrity Project and Sierra Club in the United States District Court for the District of Columbia: *Environmental Integrity Project v. McCarthy*, Case No. 1:14-cv-01196 (D.D.C.). On July 16, 2014, Plaintiffs filed this complaint alleging that Gina McCarthy, in her official capacity as Administrator of the United States Environmental Protection Agency ("EPA"), failed to perform a non-discretionary duty to grant or deny within 60 days three petitions submitted by Environmental Integrity Project and Sierra Club requesting that EPA object to three CAA Title V permits issued by the Texas Commission on Environmental Quality to Luminant Generating Company to operate three power plants in Texas. The proposed settlement agreement would establish deadlines for EPA to take such action.

DATES: Written comments on the proposed settlement agreement must be received by December 15, 2014.

ADDRESSES: Submit your comments, identified by Docket ID number EPA-HQ-OGC-2014-0825, online at www.regulations.gov (EPA's preferred method); by email to oei.docket@epa.gov; by mail to EPA Docket Center, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; or by hand delivery or courier to EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC, between 8:30 a.m. and 4:30 p.m. Monday through Friday, excluding legal holidays. Comments on a disk or CD-ROM should be formatted in Word or ASCII file, avoiding the use of special characters and any form of encryption, and may be mailed to the mailing address above.

FOR FURTHER INFORMATION CONTACT:

Karen Bianco, Air and Radiation Law Office (2344A), Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone: (202) 564-3298; fax number (202) 564-5603; email address: bianco.karen@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Additional information about the proposed settlement agreement

This proposed settlement agreement would resolve a lawsuit filed by Environmental Integrity Project and Sierra Club seeking to compel the Administrator to take actions under CAA section 505(b)(2). Under the terms of the proposed settlement agreement, EPA would agree to sign a response

addressing the following issues from Environmental Integrity Project and Sierra Club's Title V petitions by no later than January 23, 2015:

a. Petition for Objection to Texas Title V Permit No. 065 for the Operation of the Big Brown Steam Electric Station, Freestone County, Texas (Mar. 3, 2014) (attached as Exhibit 1 to the proposed settlement agreement) ("Big Brown Petition"), Issue V.A (pp. 7-14);

b. Petition for Objection to Texas Title V Permit No. 064 for the Operation of the Monticello Steam Electric Station, Titus County, Texas (Mar. 3, 2014) (attached as Exhibit 2 to the proposed settlement agreement) ("Monticello Petition"), Issue V.A (pp. 5-11); and

c. Petition for Objection to Texas Title V Permit No. 053 for the Operation of the Martin Lake Steam Electric Station in Rusk County, Texas (Feb. 24, 2014) (attached as Exhibit 3 to the proposed settlement agreement) ("Martin Lake Petition"), Issue V.A (pp. 5-9).

EPA would also agree to sign a response addressing the following issues from Environmental Integrity Project and Sierra Club's Title V petitions by no later than May 15, 2015:

a. Big Brown Petition, Issue V.D (pp. 17-20);

b. Monticello Petition, Issue V.B (pp. 11-14); and

c. Martin Lake Petition, Issue V.B (pp. 9-14).

EPA would have no obligation to respond to any issue in the title V petitions except those specifically identified. Further, under the terms of the proposed agreement, Plaintiffs would send a letter to the EPA Administrator within 60 days of the execution of the settlement agreement withdrawing the remaining portions of their Big Brown petition, namely:

a. Big Brown Petition, Issue V.B (pp. 14-15); and

b. Big Brown Petition, Issue V.C (pp. 15-17).

Under the terms of the proposed settlement agreement, EPA will expeditiously deliver notice of EPA's responses to the Office of the Federal Register for review and publication following signature of such response. In addition, the proposed settlement agreement outlines the procedure for the Plaintiffs to request costs of litigation, including attorney fees.

For a period of thirty (30) days following the date of publication of this notice, the Agency will accept written comments relating to the proposed settlement agreement from persons who are not named as parties or intervenors to the litigation in question. EPA or the Department of Justice may withdraw or withhold consent to the proposed

settlement agreement if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act. Unless EPA or the Department of Justice determines that consent to this settlement agreement should be withdrawn, the terms of the settlement agreement will be affirmed.

II. Additional Information About Commenting on the Proposed Settlement Agreement

A. How can I get a copy of the proposed settlement agreement?

The official public docket for this action (identified by Docket ID No. EPA-HQ-OGC-2014-0825) contains a copy of the proposed settlement agreement. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OEI Docket is (202) 566-1752.

An electronic version of the public docket is available through www.regulations.gov. You may use the www.regulations.gov to submit or view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select "search".

It is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing online at www.regulations.gov without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. Information claimed as CBI and other information whose disclosure is restricted by statute is not included in the official public docket or in the electronic public docket. EPA's policy is that copyrighted material, including copyrighted material contained in a public comment, will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any

of the publicly available docket materials through the EPA Docket Center.

B. How and to whom do I submit comments?

You may submit comments as provided in the **ADDRESSES** section. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment and with any disk or CD-ROM you submit. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the www.regulations.gov Web site to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an "anonymous access" system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment. In contrast to EPA's electronic public docket, EPA's electronic mail (email) system is not an "anonymous access" system. If you send an email comment directly to the Docket without going through www.regulations.gov, your email address is automatically captured and included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

Dated: November 4, 2014.

Lorie J. Schmidt,

Associate General Counsel.

[FR Doc. 2014-26866 Filed 11-12-14; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-0761, 3060-0161 and 3060-0703]

Information Collections Being Submitted for Review and Approval to the Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before December 15, 2014. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, OMB, via email Nicholas.A.Fraser@omb.eop.gov; and to Cathy Williams, FCC, via email PRA@fcc.gov and to Cathy.Williams@fcc.gov. Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page <<http://www.reginfo.gov/public/do/PRAMain>>, (2) look for the section of the Web page called “Currently Under Review,” (3) click on the downward-pointing arrow in the “Select Agency” box below the “Currently Under Review” heading, (4) select “Federal Communications Commission” from the list of agencies presented in the “Select Agency” box, (5) click the “Submit” button to the right of the “Select Agency” box, (6) when the list of FCC ICRs currently under review appears, look for the OMB control number of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0761.

Title: Section 79.1, Closed Captioning of Video Programming, CG Docket No. 05–231.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities; Individuals or households; and Not-for-profit entities.

Number of Respondents and Responses: 22,565 respondents; 1,149,437 responses.

Estimated Time per Response: 0.25 hours (15 minutes) to 120 hours.

Frequency of Response: Annual, one-time and on-occasion reporting requirements; Third party disclosure requirement; Recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this obligation is found at section 713 of the Communications Act of 1934, as amended, 47 U.S.C. 613, and implemented at 47 CFR 79.1.

Total Annual Burden: 1,254,358 hours.

Total Annual Cost: \$40,220,496.

Nature and Extent of Confidentiality: Confidentiality is an issue to the extent that individuals and households provide personally identifiable information, which is covered under the FCC’s system of records notice (SORN), FCC/CGB–1, “Informal Complaints and Inquiries.” As required by the Privacy Act, 5 U.S.C. 552a, the Commission also published a SORN, FCC/CGB–1 “Informal Complaints and Inquiries,” in the **Federal Register** on December 15, 2009 (74 FR 66356) which became effective on January 25, 2010.

Nature and Extent of Confidentiality: Confidentiality is an issue to the extent that individuals and households provide personally identifiable information. As required by the Privacy Act, 5 U.S.C. 552a, the FCC published a system of records notice (SORN), FCC/CGB–1, “Informal Complaints, Inquiries, and Requests for Dispute Assistance,” in the **Federal Register** on August 15, 2014 (79 FR 48152), which became effective on September 24, 2014.

Privacy Act Impact Assessment: The Privacy Impact Assessment (PIA) for Informal Complaints and Inquiries was completed on June 28, 2007. It may be reviewed at: http://www.fcc.gov/omd/privacyact/Privacy_Impact_Assessment.html. The Commission is in the process of updating the PIA to incorporate various revisions to it as a result of revisions to the SORN.

Needs and Uses: The Commission seeks to extend existing information collection requirements in its closed captioning rules (47 CFR 79.1), which require that, with some exceptions, all new video programming, and 75 percent of “pre-rule” programming, be closed captioned. The existing collections include petitions by video programming providers, producers, and owners for exemptions from the closed captioning rules, responses by commenters, and replies; complaints by viewers alleging violations of the closed captioning rules, responses by video programming distributors, and recordkeeping in support of complaint responses; and making video programming distributor contact information available to viewers in phone directories, on the Commission’s Web site and the Web sites of video programming distributors (if they have them), and in billing statements (to the extent video programming distributors issue them). In addition, the Commission seeks to extend proposed information collection requirements. Specifically, on February 20, 2014, the Commission adopted rules governing the quality of closed captioning on television. Closed Captioning of Video Programming; Telecommunications for the Deaf and Hard of Hearing, Inc. Petition for Rulemaking, CG Docket No. 05–231, Report and Order, Declaratory Ruling, and Further Notice of Proposed Rulemaking, 29 FCC Rcd 2221 (2014), published at 79 FR 17911 (March 31, 2014). The Commission took the following actions, among others:

(a) Required video programming distributors to make best efforts to obtain certification from video programmers that their programming (i) Complies with the captioning quality standards established in the Report and

Order; (ii) adheres to the Best Practices for video programmers set out in the Report and Order; or (iii) is exempt from the closed captioning rules under one or more properly attained and specified exemptions.

(b) Adopted additional requirements and a “compliance ladder” for broadcasters that use electronic newsroom technique.

(c) Required video programming distributors to keep records of their activities related to the maintenance, monitoring, and technical checks of their captioning equipment.

(d) Required that petitions requesting an exemption based on the economically burdensome standard and all subsequent pleadings, as well as comments, oppositions, or replies to comments, be filed electronically in accordance with 47 CFR 0.401(a)(1)(iii) instead of as a paper filing. Comments, oppositions, or replies to comments must be served on the other party, by delivering or mailing a copy to the last known address in accordance with 47 CFR 1.47 or by sending a copy to the email address last provided by the party, its attorney, or other duly constituted agent, and must include a certification that the other party was served with a copy.

OMB Control Number: 3060–0161.

Title: Section 73.61, AM Directional Antenna Field Strength Measurements.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business and other for-profit entities.

Number of Respondents and Responses: 2,268 respondents and 2,268 responses.

Estimated Time per Response: 4–50 hours.

Frequency of Response: Recordkeeping requirement.

Total Annual Burden: 36,020 hours.

Total Annual Cost: None.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in Sections 154(i) and 303 of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Impact Assessment: No impact(s).

Needs and Uses: 47 CFR 73.61 requires that each AM station using directional antennas to make field strength measurement as often as necessary to ensure proper directional antenna system operation. Stations not having approved sampling systems

make field strength measurements every three months. Stations with approved sampling systems must take field strength measurements as often as necessary. Also, all AM stations using directional signals must take partial proofs of performance as often as necessary. The FCC staff used the data in field inspections/investigations. AM licensees with directional antennas use the data to ensure that adequate interference protection is maintained between stations and to ensure proper operation of antennas.

OMB Control Number: 3060-0703.

Title: Determining Costs of Regulated Cable Equipment and Installation, FCC Form 1205.

Form Number: FCC Form 1205.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 4,000 respondents; 6,000 responses.

Estimated Time per Response: 4–12 hours.

Frequency of Response: Recordkeeping requirement, Annual reporting requirement, Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in Section 301(j) of the Telecommunications Act of 1996 and 623(a)(7) of the Communications Act of 1934, as amended.

Total Annual Burden: 52,000 hours.

Total Annual Cost: \$1,800,000.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: Information derived from FCC Form 1205 filings is used to facilitate the review of equipment and installation rates. This information is then reviewed by each cable system's respective local franchising authority. Section 76.923 records are kept by cable operators in order to demonstrate that charges for the sale and lease of equipment for installation have been developed in accordance with the Commission's rules.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of the Managing Director.

[FR Doc. 2014-26792 Filed 11-12-14; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the Federal Deposit Insurance Corporation's Board of Directors will meet in open session at 10:00 a.m. on Tuesday, November 18, 2014, to consider the following matters:

SUMMARY AGENDA: No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Disposition of minutes of previous Board of Directors' Meetings.

Memorandum and resolution re: Regulatory Capital Rules: Regulatory Capital, Proposed Revisions to the Advanced Approaches Risk-Based Capital Rule.

Memorandum and resolution re: Final Rule To Adjust the Timing of the Annual Stress Testing Cycle.

Memorandum and resolution re: Notice of Proposed Rulemaking: Filing Requirements and Processing Procedures for Changes in Control with Respect to State Nonmember Banks and State Savings Associations.

Summary reports, status reports, reports of the Office of Inspector General, and reports of actions taken pursuant to authority delegated by the Board of Directors.

DISCUSSION AGENDA:

Memorandum and resolution re: Final Rule on Revisions to the Deposit Insurance Assessment System.

The meeting will be held in the Board Room temporarily located on the fourth floor of the FDIC Building located at 550 17th Street NW., Washington, DC

This Board meeting will be Webcast live via the Internet and subsequently made available on-demand approximately one week after the event. Visit <https://fdic.primevideo.com/#/channel/1232003497484/Board+Meetings> to view the event. If you need any technical assistance, please visit our Video Help page at: <http://www.fdic.gov/video.html>.

The FDIC will provide attendees with auxiliary aids (e.g., sign language interpretation) required for this meeting. Those attendees needing such assistance should call 703-562-2404 (Voice) or 703-649-4354 (Video Phone) to make necessary arrangements.

Requests for further information concerning the meeting may be directed

to Mr. Robert E. Feldman, Executive Secretary of the Corporation, at 202-898-7043.

Dated: November 10, 2014.

Federal Deposit Insurance Corporation

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2014-27044 Filed 11-10-14; 4:15 pm]

BILLING CODE 6714-01-P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

AGENCY: Federal Election Commission.

DATE AND TIME: Tuesday November 18, 2014 at 10:00 a.m.

PLACE: 999 E Street NW., Washington, DC.

STATUS: This meeting will be closed to the public.

Items To Be Discussed

Compliance matters pursuant to 2 U.S.C. 437g.

Matters concerning participation in civil actions or proceedings or arbitration. Information the premature disclosure of which would be likely to have a considerable adverse effect on the implementation of a proposed Commission action.

Internal personnel rules and internal rules and practices.

* * * * *

PERSON TO CONTACT FOR INFORMATION:

Judith Ingram, Press Officer, Telephone: (202) 694-1220.

Shelley E. Garr,

Deputy Secretary of the Commission.

[FR Doc. 2014-26996 Filed 11-10-14; 4:15 pm]

BILLING CODE 6715-01-P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984.

Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (www.fmc.gov) or by contacting the Office of Agreements at (202) 523-5793 or tradeanalysis@fmc.gov.

Agreement No.: 011733-034.

Title: Common Ocean Carrier Platform Agreement.

Parties: A.P. Moller-Maersk A/S; CMA CGM; Hamburg-Süd; Hapag-Lloyd AG;

Mediterranean Shipping Company S.A.; and United Arab Shipping Company (S.A.G.) as shareholder parties, and American President Lines, Ltd., APL Co., Pte Ltd.; Alianca Navegacao e Logistica Ltda.; China Shipping Container Lines Company Limited; Compania Chilena de Navegacion Interocanica S.A.; Compania Sud Americana de Vapores, S.A.; Companhia Libra de Navegacao; COSCO Container Lines Co., Ltd.; Emirates Shipping Lines; Evergreen Line Joint Service Agreement; Gold Star Line, Ltd.; Hanjin Shipping Co., Ltd.; Hyundai Merchant Marine Co. Ltd; Industrial Maritime Carriers, LLC; Kawasaki Kisen Kaisha, Ltd.; MISC Berhad; Mitsui O.S.K. lines Ltd.; Nippon Yusen Kaisha; Norasia Container Lines Limited; Safmarine MPV N.V.; Tasman Orient Line C.V.; U.S. Ocean, LLC; Yang Ming Marine Transport Corporation and Zim Integrated Shipping Services, Ltd. as non-shareholder parties.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor; 1627 I Street NW., Suite 1100; Washington, DC 20006.

Synopsis: The amendment corrects the address of APL Co. Pte Ltd.

Agreement No.: 012190-002.

Title: HSDG-GWF Space Charter Agreement.

Parties: Hamburg Sud and Great White Fleet Liner Services Ltd.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor; 1627 I Street NW., Suite 1100; Washington, DC 20006-4007.

Synopsis: The amendment extends the duration of the agreement and updates the title of the contact person for one of the parties.

Agreement No.: 012301.

Title: Siem Car Carrier Pacific AS/ Volkswagen Logistics GMBH & Co. Space Charter Agreement.

Parties: Siem Car Carrier Pacific AS and Volkswagen Logistics GMBH & Co.

Filing Party: Ashley W. Craig, Esq. and Elizabeth K. Lowe, Esq.; Venable LLP; 575 Seventh Street NW., Washington, DC 20004.

Synopsis: The agreement authorizes the parties to engage in a limited range of cooperative activities, including but not limited to, vessel space chartering in the trade between the U.S. West Coast and Mexico.

Agreement No.: 012302.

Title: UASC/HSDG Space Charter Agreement.

Parties: United Arab Shipping Company (S.A.G.); and Hamburg Sud KG.

Filing Party: Wayne Rohde, Esq.; Cozen O'Connor; 1627 I Street NW., Suite 1100; Washington, DC 20006.

Synopsis: The agreement authorizes UASC to charter space to HSDG in the trade between Asia and Egypt, on the one hand, and the U.S. East and West Coasts, on the other hand.

By Order of the Federal Maritime Commission.

Dated: November 7, 2014.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2014-26859 Filed 11-12-14; 8:45 am]

BILLING CODE 6730-01-P

FEDERAL TRADE COMMISSION

[File No. 142 3003]

MPHJ Technology Investments, LLC, Jay Mac Rust, and Farney Daniels, P.C.; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before December 8, 2014.

ADDRESSES: Interested parties may file a comment at <https://ftcpublic.commentworks.com/ftc/mphtechconsent> online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write “MPHJ Technology Investments, LLC, et al—Consent Agreement; File No. 142 3003” on your comment and file your comment online at <https://ftcpublic.commentworks.com/ftc/mphtechconsent> by following the instructions on the web-based form. If you prefer to file your comment on paper, write “MPHJ Technology Investments, LLC, et al—Consent Agreement; File No. 142 3003” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

SUPPLEMENTARY INFORMATION section below. Write “MPHJ Technology Investments, LLC, et al—Consent Agreement; File No. 142 3003” on your comment and file your comment online at <https://ftcpublic.commentworks.com/ftc/mphtechconsent> by following the instructions on the web-based form. If you prefer to file your comment on paper, write “MPHJ Technology Investments, LLC, et al—Consent Agreement; File No. 142 3003” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Daniel O. Hanks (202-326-2472) or

Michael Tankersley (202-326-2991), Bureau of Consumer Protection, 600 Pennsylvania Avenue NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for November 6, 2014), on the World Wide Web, at <http://www.ftc.gov/os/actions.shtm>.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before December 8, 2014. Write “MPHJ Technology Investments, LLC, et al—Consent Agreement; File No. 142 3003” on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at <http://www.ftc.gov/os/publiccomments.shtm>. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any “[t]rade secret or any commercial or financial information which . . . is privileged or confidential,” as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices,

manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).¹ Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at <https://ftcpublic.commentworks.com/ftc/mphtechconsent> by following the instructions on the web-based form. If this Notice appears at <http://www.regulations.gov/#/home>, you also may file a comment through that Web site.

If you file your comment on paper, write "MPHJ Technology Investments, LLC, et al—Consent Agreement; File No. 142 3003" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at <http://www.ftc.gov> to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before December 8, 2014. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at <http://www.ftc.gov/ftc/privacy.htm>.

¹ In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c), 16 CFR 4.9(c).

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission (the "Commission") has accepted, subject to approval, an agreement containing a consent order from MPHJ Technology Investments, LLC; Jay Mac Rust; and Farney Daniels, P.C. (the "Respondents").

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

This matter concerns allegedly deceptive representations that the Respondents made in a campaign of letters sent to thousands of small businesses across the United States in an attempt to sell licenses for certain U.S. patents. The complaint alleges that the Respondents made false or unsubstantiated representations in their letters that many small businesses had already agreed to pay thousands of dollars for such licenses. The complaint also alleges that the Respondents' letters falsely represented that a patent infringement lawsuit would be filed against the recipient if it did not respond to the letter, and that this suit would be filed imminently. The complaint alleges that these representations constitute deceptive acts or practices in violation of Section 5 of the Federal Trade Commission Act.

The proposed consent order contains provisions designed to prevent the Respondents from engaging in similar acts and practices in the future. Section I.A of the proposed order would prohibit false or unsubstantiated representations that a patent has been licensed in substantial numbers, at particular prices, or within particular price ranges. Section I.B of the proposed order would prohibit false or unsubstantiated representations about the licenses for a patent or the responses of recipients of patent assertion communications, or concerning the results of licensing, sales, settlement, or litigation of a patent. Section I.C would prohibit misrepresentations that the Respondents or an affiliate of the Respondents has initiated a lawsuit. And Section I.D would prohibit representations that the Respondents or an affiliate of the Respondents will initiate a lawsuit unless they have decided to take such action and they

possess competent and reliable evidence sufficient to substantiate that they are prepared and able to do so. In determining whether such a representation was substantiated at the time that it was made, evidence that an action was not taken because of a change in circumstances or information obtained subsequent to making the representation shall be considered.

These prohibitions in the proposed consent order apply to communications (other than filings in a lawsuit or correspondence between counsel in a lawsuit) that state that the intended recipient or anyone affiliated with the intended recipient is or may be infringing rights arising from a patent, is or may be obligated to obtain a license because of a patent, or owes or may owe compensation to another because of a patent.

The proposed consent order also contains reporting and compliance provisions. Section II requires the Respondents to maintain and upon request make available certain compliance-related records. Sections III through VI requires the Respondents to deliver a copy of the order to officers, employees, and representatives having managerial responsibilities with respect to the order's subject matter, notify the Commission of changes in corporate structure that might affect compliance obligations, and file compliance reports with the Commission.

Section VII of the proposed order provides that, with certain exceptions, the order will terminate in twenty years.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or the proposed order, or to modify in any way the proposed order's terms.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2014-26803 Filed 11-12-14; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Intent To Award Ebola Response Outbreak Funding to the International Association of National Public Health Institutes (IANPHI)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice provides public announcement of CDC's intent to award Ebola appropriations to the International Association of National Public Health Institutes (IANPHI) for response to the Ebola outbreak funding. This award was proposed in Fiscal Year (FY) 2015 under funding opportunity announcement GH14-1419 "Advancing National Public Health Institutes Globally". IANPHI is uniquely positioned, in terms of authority, ability, track record, infrastructure, and credibility to engage its member institutes to respond to the Ebola outbreak in West Africa. Furthermore, these activities to increase eligible governments' capacity to respond to the Ebola outbreak are directly aligned with the current activities that IANPHI is conducting under this FOA to strengthen and expand national public health institute capabilities and support global health security.

Catalogue of Federal Domestic Assistance Number (CFDA): 93.318.

Authority: Sections 307 and 317(k)(2), Public Health Service Act 42 U.S.C. 242l and 247b(k)(2) as amended.

Single award may be awarded to grantee totaling \$1,100,000 for Ebola response outbreak.

Funding is appropriated under the Continuing Appropriations Resolution, 2015, Public Law 113-164, 128 Stat. 1867 (2014).

DATES: Anticipated award date is 12/1/2014.

Application Due Date: 11/17/2014.

Project Number is CDC-RFA-GH14-1419.

ADDRESSES: CDC has waived the Grants.gov electronic submission process for this requirement. Recipients are hereby authorized to submit a paper copy application for (CDC-RFA-GH14-1419) via Express Mail (i.e. FedEx, UPS, or DHL) and send the application via email. Mailed applications must be addressed to Dionne Bounds, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341, telephone (770) 488-2082, or email her at DBounds@cdc.gov. The application must include a detailed line-item budget and justification to support the Ebola activities from December 1, 2014 to September 29, 2015.

Please download the following to complete the application package:

http://apply07.grants.gov/apply/forms/sample/SF424_2_1-V2.1.pdf—

Application Package
<http://www.cdc.gov/od/pgo/funding/docs/CertificationsForm.pdf>—
 Certifications

<http://www.cdc.gov/od/pgo/funding/grants/foamain.shtm>—Assurances
http://www.cdc.gov/od/pgo/funding/grants/Budget_Preparation_Guidelines_8-2-12.docx—CDC-PGO Budget Guidelines
<http://apply07.grants.gov/apply/forms/sample/SF424A-V1.0.pdf>—SF-424A Budget Information

All applications must be submitted to and received by the Grants Management Officer (GMO) no later than 11:59 p.m. EST on November 17, 2014 and please provide the GMO a PDF version of the application by email to the following email address: ogsghebolaresponse@cdc.gov subject line: CDC-RFA-GH14-1419.

Applicants will be provided with the Funding Opportunity Announcement (FOA) and additional application submission guidance via email notification. Applicants may contact the POCs listed with questions regarding the application process.

FOR FURTHER INFORMATION CONTACT:

For programmatic or technical assistance: Miranda Bodfish, Project Officer, Department of Health and Human Services, Centers for Disease Control and Prevention, 1600 Clifton Rd. MS E-93, Atlanta, GA 30333, Telephone: 404 719-0232, email: WT14@cdc.gov.

For financial, awards management, or budget assistance: Dionne Bounds, Grants Management Officer, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341, Telephone (770) 488-2082, email: DBounds@cdc.gov.

SUPPLEMENTARY INFORMATION: The purpose of this notice is to solicit an application from IANPHI to assist in the response to the Ebola virus in West Africa. The funding will support the impacted surrounding countries to combat this health crisis. This funding will target the following countries: Cameroon, Cote d'Ivoire, Guinea, and Guinea-Bissau to support the responses of the CDC to the outbreak of Ebola virus in West Africa. This funding will enable the U.S. to provide unified mobilization to address a crisis of this magnitude. CDC will continue to build partnerships and strengthen existing projects to respond to Ebola. CDC and its partners will help to address the need for surveillance, detection, coordination, response, and increase eligible governments' capacity to respond to the Ebola outbreak.

Award Information

Type of Award: Expansion Supplement.

Approximate Total Current Fiscal Year Funding: \$1,100,000.

Anticipated Number of Awards: One.
Fiscal Year Funds: 2015.

Anticipated Award Date: December 1, 2014.

Application Selection Process:

Funding will be awarded to applicant based on results from the technical review recommendation.

Dated: November 6, 2014.

Ron A. Otten,

Acting Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2014-26799 Filed 11-7-14; 11:15 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Administration for Children and Families****Submission for OMB Review; Comment Request**

Title: Objective Work Plan (OWP) and Objective Progress Report (OPR).

OMB No.: 0970-0429.

Description: Content and formatting changes are being made to the OPR and OWP. The information in OPR is currently collected on quarterly basis to monitor the performance of grantees and better gauge grantee progress. The OWP is used by applicants when they submit their proposals and then by grantees to monitor their projects once the award is made by ANA. ANA has determined that the requirement for ANA grantees to submit information about the project activities on quarterly basis creates undue burden for Grantees. Therefore, ANA has reformatted the OPR to require Grantees submit semi-annual reports instead of quarterly report. This will reduce the administrative burden on Grantees, especially the smaller organizations. The majority of content being requested from the grantees essentially remain same except for the frequency of reporting.

OPR: The following are proposed content changes to the document:

Grantee Information: Report Frequency—This section of OPR will be reformatted to request semi-annual or final project data instead of quarterly information. The other sections of the document with reference to "quarterly" information will be changed to reflect the shift from four-times a year reporting requirement to twice per year.

Objective Work Plan Update: Content remains the same. No changes are proposed for this section of the OPR.

Impact indicator: Current Status of Expected Results and Current Status of Expected Benefits which are reported separately on the OPR will be combined

to read "Current Status of Expected Results and Benefits." The content requested in this section is similar to the previous OPR without the added burden of having the reporting organizations provide the analysis that distinguish between "results and benefits". Every section of the document will be rewritten to reflect this change.

OWP: ANA proposes to reformat the OWP (content is same) by swapping the Objective field with Problem Statement. In other words, this section will require respondents to begin with a concise statement about the problem the project is designed to address and will be followed by more details about the objectives of the project.

The two fields "Results Expected and Benefits Expected" will be combined into one field to read "Results and benefits Expected". This will reduce redundancy and help reduce the burden on Grantees.

Respondents: Tribal Government, Native non-profit organizations, Tribal Colleges & Universities.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OWP	500	1	3	1,500
OPR	275	2	1	550

Estimated Total Annual Burden Hours: 2,050.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendation for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202-395-7285, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014-26785 Filed 11-12-14; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

Science Board to the Food and Drug Administration Advisory Committee Meeting; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Science Board to the Food and Drug Administration. This meeting was announced in the **Federal Register** of October 8, 2014. The amendment is being made to reflect changes in URL for the Webcast. There are no other changes.

FOR FURTHER INFORMATION CONTACT:

Martha Monser, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3309, Silver Spring, MD 20993, 301-796-4627, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 8, 2014 (79 FR 60856), FDA announced that a meeting of the Science Board to the Food and Drug Administration would be held on November 19 and 20, 2014. On page 60857, in the first column, the URL information is changed to read as follows:

The link for the Webcast on November 19, 2014, is available at: <https://collaboration.fda.gov/scienceboard111914/>. The link for the Webcast on November 20, 2014, is available at: <https://collaboration.fda.gov/scienceboard112014>.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: November 5, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014-26821 Filed 11-12-14; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1732]

Food Advisory Committee; Notice of Meeting; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of the meeting of the Food Advisory Committee. This meeting was announced in the **Federal Register** of August 19, 2014. The amendment is being made to add an **ADDRESSES** section and to reflect a change in the *Agenda*. There are no other changes.

FOR FURTHER INFORMATION CONTACT:

Karen Strambler, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2589, FAX: 301-436-2637, email: FoodAdvisoryCommittee@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area) and follow the prompts to the desired Center or product area. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 19, 2014 (79 FR 49091), FDA announced that a meeting of the Food Advisory

Committee would be held on December 16–17, 2014. The **ADDRESSES** portion of the document is to read as follows:

ADDRESSES: FDA is opening a docket for public comment on this meeting. The docket will open for public comment on November 13, 2014. The docket will close on January 15, 2014. Interested persons may submit either electronic comments regarding this meeting to <http://www.regulations.gov> or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>. All comments received will be posted without changes, including any personal information provided. Comments received on or before December 1, 2014, will be provided to the committee before the meeting.

On page 49091, in the second column, the *Agenda* portion of the document is changed to read as follows:

Agenda: The committee will discuss how risk assessments should account for the susceptibility to the effects of a particular chemical exposure because of factors such as genetics, age, sex, and health status and the circumstances under which FDA would decide to conduct a separate risk assessment for these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: November 7, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–26823 Filed 11–12–14; 8:45 am]

BILLING CODE 4164–01–P

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than January 12, 2015.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 10C–03, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Evaluation and Initial Assessment of the HRSA Teaching Health Centers Graduate Medical Education Program.

OMB No.: 0906–xxxx—New.

Abstract: Section 5508 of the Affordable Care Act of 2010 amended section 340H of the Public Health Service Act to establish the Teaching Health Center Graduate Medical Education (THCGME) program to provide funding support for new and the expansion of existing primary care residency training programs in community-based settings. The primary goals of this program is to increase the production of primary care providers who are better prepared to practice in community settings, particularly with underserved populations, and improve the geographic distribution of primary care providers.

Statute requires the Secretary to determine an appropriate THCGME program payment for indirect medical expenses (IME) as well as to update, as deemed appropriate, the per resident

amount used to determine the Program's payment for direct medical expenses (DME). To inform these determinations and to increase understanding of this model of residency training, the George Washington University (GW) is conducting an evaluation of the costs associated with training residents in the Teaching Health Center (THC) model. GW has developed a standardized costing instrument to gather data from all THCGME programs. The information gathered in the standardized costing instrument includes, but is not limited to, resident and faculty full-time equivalents, salaries and benefits, residency administration costs, educational costs, residency clinical operations and administrative costs, and patient visits and clinical revenue generated by medical residents.

Need and Proposed Use of the Information: HRSA is collecting costing information related to both DME and IME in an effort to establish a THC's total cost of running a residency program, to assist the Secretary in determining an appropriate update to the per resident amount used to calculate the payment for DME and an appropriate IME payment. The described data collection activities will serve to inform these statutory requirements for the Secretary in a uniform and consistent manner.

Likely Respondents: THCGME grantees.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

The annual estimate of burden is as follows:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Teaching Health Center Costing Instrument	60	1	60	10	600
Total	60	1	60	10	600

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Dated: October 31, 2014.

Jackie Painter,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2014-26854 Filed 11-12-14; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than December 15, 2014.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to 202-395-5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests

submitted to OMB for review, email the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443-1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report OMB No. 0915-0172—Revision.

Abstract: The Health Resources and Services Administration (HRSA) is revising the *Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report*. The Guidance is used annually by the 50 states and nine jurisdictions in applying for Block Grants under Title V of the Social Security Act and in preparing the required Annual Report. In partnership with the leadership in State Title V Maternal and Child Health (MCH) programs as well as with other national MCH leaders and stakeholders, HRSA's Maternal and Child Health Bureau (MCHB) has been working over the past year to develop and refine a vision for transforming the MCH Block Grant to States program to better meet current and future challenges facing our nation's mothers and children, including children with special health care needs (CSHCN) and their families. The proposed revisions to the Application and Annual Reporting requirements and to the data forms that are contained in the revised guidance reflect this transformative vision.

Relative to the state's submission of a yearly Application, Annual Report and 5-year Needs Assessment, the aims of the MCH Block Grant to States program transformation are threefold: (1) Reduce burden to states, (2) maintain state flexibility, and (3) improve accountability. Revisions to this edition are intended to enable the state to tell a more cohesive and comprehensive Title V story and to better reflect on the program's leadership role and its contributions to the state's public health system in building improved and expanded systems of care for the MCH population. It is recognized that the full extent of the anticipated burden reduction will be realized over time as states become more familiar with the

new instructions and reporting requirements. The burden estimates presented in the table below are based on previous burden estimates, consultations with a few states on the proposed changes, and comments received during the 60-day public comment period.

Specific changes to this edition of the *Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report* include the following:

(1) Narrative reporting will be organized by six population health domains (i.e., Women's/Maternal Health; Perinatal/Infant's Health; Child Health; CSHCN; Adolescent Health and Cross-cutting or Life Course); (2) Revised National Performance Measure (NPM) framework will be implemented with states selecting 8 of 15 NPMs for their programmatic focus; (3) state-level program data, such as breakdowns of MCH populations by race/ethnicity, health indicator data, and national performance and outcome measure data will be provided by MCHB, as available, from national data sources, thus, reducing the annual reporting burden for states; (4) Given that most MCH issues are multifactorial, the state will establish evidence based or evidence informed strategies to address each of the selected NPMs and will report on one or more of the Evidence-based or informed Strategy Measures (ESMs) developed for each NPM; (5) Revised instructions and the inclusion of a logic model for the State Title V MCH Block Grant Application/Annual Report process will provide greater emphasis on the need for the state priority needs and national MCH priority areas to drive the state's reporting on the 5-year (and ongoing) Needs Assessment findings, the selection of eight (8) NPMs which target the state-identified priority needs, the development of evidence based or informed strategies and related ESMs for addressing each of the selected NPMs, and the establishment of between three (3) and five (5) State Performance Measures (SPMs) which respond to the state's identified unique needs; (6) State Application/Annual Report will include a 5-year Action Plan for addressing the identified MCH priority areas; (7) An

Executive Summary (up to five pages in length) will be included with each submitted Application/Annual Report; (8) A 5-year Needs Assessment Summary (up to 20 pages in length) will be integrated into the state's MCH Block Grant Application/Annual Report and will replace the more comprehensive, stand-alone 5-year Needs Assessment document that the state previously submitted; (9) Health System Capacity Indicators will be eliminated; and (10) Federal and State Title V program budget and expenditures will be reported separately by the state.

Need and Proposed Use of the Information: Each year, all states and jurisdictions are required to submit an Application/Annual Report for federal funds for their Title V MCH Services Block Grant to States Program to the

HRSA's MCHB [Section 505(a) of Title V of the Social Security Act.] In addition, the state/jurisdictional MCH Block Grant programs are required to conduct a statewide, comprehensive Needs Assessment every 5 years. The information and instructions for the preparation and submission of this Application/Annual Report are contained in the *Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report*.

Likely Respondents: By legislation [Section 505(a) of Title V of the Social Security Act], the MCH Block Grant Application/Annual Report must be developed by, or in consultation with, the state MCH Health agency.

Burden Statement: Burden in this context means the time expended by

persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Burden per response (in hours)	Total burden hours
Application and Annual Report without 5-Year Needs Assessment	59	1	59	123	7,257
Application and Annual Report with 5-Year Needs Assessment	59	1	59	189.3	11,169
Average Total Annual Burden	59	59	*8,561

* Reflects the average of one Application/Annual Report with Needs Assessment and two Application/Annual Reports without Needs Assessment

In fiscal year (FY) 2016, states and jurisdictions will be submitting an application and annual report with a 5-year Needs Assessment for a total estimated burden of 11,169 hours. In FY 2017 and FY 2018, states and jurisdictions will be submitting an Application and Annual Report without a 5-year needs assessment for a total estimated burden of 14,514.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Dated: October 31, 2014

Jackie Painter,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2014-26855 Filed 11-12-14; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel, NEI Anterior Eye and Glaucoma Grant Applications.

Date: December 1, 2014.

Time: 1:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Suite 1300, 5635 Fishers Lane, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Brian Hoshaw, Ph.D., Scientific Review Officer, National Eye Institute, National Institutes of Health, Division of Extramural Research, 5635 Fishers Lane, Suite 1300, Rockville, MD 20892; 301-451-2020; hoshawb@mail.nih.gov

Name of Committee: National Eye Institute Special Emphasis Panel, NEI Pediatric, Glaucoma and Neuro-Ophthalmology Grant Applications.

Date: December 3, 2014.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Suite 1300, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Brian Hoshaw, Ph.D., Scientific Review Officer, National Eye Institute, National Institutes of Health, Division of Extramural Research, 5635 Fishers Lane, Suite 1300, Rockville, MD 20892; 301-451-2020; hoshawb@mail.nih.gov

Name of Committee: National Eye Institute Special Emphasis Panel, NEI Retinal Disease Epigenetic Grant Applications.

Date: December 5, 2014.

Time: 2:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Suite 1300, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jeanette M. Hosseini, Ph.D., Scientific Review Officer, National Eye Institute, National Institutes of Health, Division of Extramural Research, 5635 Fishers Lane, Suite 1300, Rockville, MD 20892; 301-451-2020; hoshawb@mail.nih.gov.

Name of Committee: National Eye Institute Special Emphasis Panel, NEI Audacious Goal Initiative RFA—U01 Grant Applications.

Date: December 11, 2014.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Suite 1300, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Anne Schaffner, Ph.D., Chief, Scientific Review Branch, National Eye Institute, National Institutes of Health, Division of Extramural Research, 5635 Fishers Lane, Suite 1300, Rockville, MD 20892; 301-451-2020; hoshawb@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: November 6, 2014.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014-26752 Filed 11-12-14; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary and Alternative Medicine; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Complementary and Alternative Medicine Special Emphasis Panel. Methods Development in Natural Products Chemistry (SBIR/STTR).

Date: December 9, 2014.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Peter Kozel, Ph.D., Scientific Review Officer, NCCAM, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892-5475; 301-496-8004; kozelp@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS.)

Dated: November 6, 2014.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014-26751 Filed 11-12-14; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R1-ES-2014-N229;
FXES11130100000-156-FF01E00000]

Endangered Species; Recovery Permit Application

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following application for a recovery permit to conduct activities with the purpose of enhancing the survival of an endangered species. The Endangered Species Act of 1973, as amended (Act), prohibits certain activities with endangered species unless a Federal permit allows such activity. The Act also requires that we invite public comment before issuing such permits.

DATES: To ensure consideration, please send your written comments by December 15, 2014.

ADDRESSES: Program Manager for Restoration and Endangered Species Classification, Ecological Services, U.S. Fish and Wildlife Service, Pacific Regional Office, 911 NE 11th Avenue, Portland, OR 97232-4181. Please refer to the permit number for the application when submitting comments.

FOR FURTHER INFORMATION CONTACT: Colleen Henson, Fish and Wildlife Biologist, at the above address, or by telephone (503-231-6131) or fax (503-231-6243).

SUPPLEMENTARY INFORMATION:

Background

The Act (16 U.S.C. 1531 *et seq.*) prohibits certain activities with respect to endangered and threatened species unless a Federal permit allows such activity. Along with our implementing regulations in the Code of Federal Regulations (CFR) at 50 CFR part 17, the Act provides for certain permits, and requires that we invite public comment before issuing these permits for endangered species.

A permit granted by us under section 10(a)(1)(A) of the Act authorizes the permittee to conduct activities (including take or interstate commerce) with respect to U.S. endangered or threatened species for scientific purposes or enhancement of propagation or survival. Our regulations implementing section 10(a)(1)(A) of the Act for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Application Available for Review and Comment

We invite local, State, and Federal agencies and the public to comment on the following application. Please refer to the permit number for the application when submitting comments.

Documents and other information submitted with this application are available for review by request from the Program Manager for Restoration and Endangered Species Classification at the address listed in the **ADDRESSES** section of this notice, subject to the requirements of the Privacy Act (5 U.S.C. 552a) and the Freedom of Information Act (5 U.S.C. 552).

Permit Number: TE-49208B

Applicant: Tammy Summers, Rainbow Connection Research, Saipan, Commonwealth of the Northern Marianas Islands.

The applicant requests a new permit to take (monitor and excavate nests, deploy nest temperature loggers, handle, measure, weigh, tag, attach transmitters, collect biological samples, salvage, photograph, and videograph) the hawksbill sea turtle (*Eretmochelys imbricata*) throughout the Commonwealth of the Northern Marianas Islands, in conjunction with research and educational activities, for the purpose of enhancing the species' survival.

Public Availability of Comments

All comments and materials we receive in response to this request will

be available for public inspection, by appointment, during normal business hours at the address listed in the **ADDRESSES** section.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

We provide this notice under section 10 of the Act (16 U.S.C. 1531 *et seq.*).

Dated: November 4, 2014.

Richard Hannan,

Regional Director, Pacific Region, U.S. Fish and Wildlife Service.

[FR Doc. 2014–26833 Filed 11–12–14; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX15EE000101100]

Agency Information Collection

Activities: Request for Comments on the ISO Geospatial Metadata Editors Registry

AGENCY: U.S. Geological Survey (USGS), Interior.

ACTION: Notice of a new information collection, ISO Geospatial Metadata Editors Registry.

SUMMARY: We (the U.S. Geological Survey) are notifying the public that we have submitted to the Office of Management and Budget (OMB) the information collection request (ICR) described below. To comply with the Paperwork Reduction Act of 1995 (PRA) and as part of our continuing efforts to reduce paperwork and respondent burden, we invite the general public and other Federal agencies to take this opportunity to comment on this ICR.

DATES: To ensure that your comments on this ICR are considered, OMB must receive them on or before December 15, 2014.

ADDRESSES: Please submit your written comments on this information collection directly to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Desk Officer for the Department of the Interior, via email: (OIRA_SUBMISSION@omb.eop.gov); or

by fax (202) 395–5806; and identify your submission with ‘OMB Control Number 1028–NEW ISO Geospatial Metadata Editors Registry’. Please also forward a copy of your comments to the Information Collection Clearance Officer, U.S. Geological Survey, 807 National Center, 12201 Sunrise Valley Drive, Reston, VA 20192 (mail); 703–648–7195 (fax); or gs-info_collections@usgs.gov (email). Please reference ‘OMB Information Collection 1028–NEW ISO Geospatial Metadata Editors Registry’ in all correspondence.

FOR FURTHER INFORMATION CONTACT:

Jennifer Carlino, Federal Geographic Data Committee Office of the Secretariat, at (303) 202–4260 or jcarlino@usgs.gov; or by mail at U.S. Geological Survey, P.O. Box 25046, Mailstop 302, Denver, CO 80225. You may also find information about this ICR at www.reginfo.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

As National Spatial Data Infrastructure (NSDI) stakeholders move forward with the implementation of the International Organization for Standardization’s (ISO) 191xx series of geospatial metadata standards, there is increasing demand for information about applications/editors that can be used to create ISO compliant metadata records. The USGS, through the Federal Geographic Data Committee (FGDC) Office of the Secretariat (www.fgdc.gov), proposes development of an online registration system for developers of ISO Geospatial Metadata Editors to voluntarily describe their metadata tools. Developers will be asked to include information such as features of the editor, its functionality, supported standards, and point of contact information through a login-based, online form. The FGDC Metadata Working Group (MWG) (www.fgdc.gov/participation/working-groupssubcommittees/mwg), whose membership represents Federal, State, Local and Tribal governments and the Private Sector, has requested the development of the registry as a useful tool to learn about available ISO Geospatial Metadata Editors. Since the information about the editors may be of interest or utility to others implementing ISO geospatial metadata standards, the FGDC will make the information collected available on the Web in the form of a simple registry type database. FGDC MWG members as well as non FGDC MWG members including geospatial metadata implementers from private sector, academia, all forms of government, and

the general public, will have read-only access to the editor information published in the registry.

II. Data

OMB Control Number: 1028–NEW.
Title: ISO Geospatial Metadata Editors Registry.

Type of Request: Approval of a new information collection.

Respondent Obligation: None.

Participation is voluntary.

Frequency of Collection: Annually.

Description of Respondents: Federal, State, Local and Tribal governments, Private Sector, and others involved in the development of ISO geospatial metadata.

Estimated Total Number of Annual Responses: Approximately 10.

Estimated Time per Response: We estimate that it will take 1 hour per person to document a single editor for inclusion in the Registry.

Estimated Annual Burden Hours: 10 hours in year one and less than 5 in each subsequent year.

Estimated Reporting and Recordkeeping “Non-Hour Cost”

Burden: There are no “non-hour cost” burdens associated with this collection of information.

Public Disclosure Statement: The PRA (44 U.S.C. 3501, *et seq.*) provides that an agency may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number. Until the OMB approves a collection of information, you are not obliged to respond.

Comments: On May 15, 2014, we published a **Federal Register** notice (79 FR 11199) announcing that we would submit this ICR to OMB for approval and soliciting comments. The comment period closed on July 14, 2014. We received no comments.

III. Request for Comments

We again invite comments concerning this ICR as to: (a) Whether the proposed collection of information is necessary for the agency to perform its duties, including whether the information is useful; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) how to enhance the quality, usefulness, and clarity of the information to be collected; and (d) how to minimize the burden on the respondents, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this notice are a matter of public record. Before including your personal mailing address, phone

number, email address, or other personally identifiable information in your comment, you should be aware that your entire comment, including your personally identifiable information, may be made publicly available at any time. While you can ask the OMB in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Kenneth M. Shaffer,

Deputy Executive Director, Federal Geographic Data Committee, Office of the Secretariat, U.S. Geological Survey.

[FR Doc. 2014-26858 Filed 11-12-14; 8:45 am]

BILLING CODE 4311-AM-P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX15EE000101100]

Announcement of National Geospatial Advisory Committee Meeting

AGENCY: U.S. Geological Survey, Interior.

ACTION: Notice of meeting.

SUMMARY: The National Geospatial Advisory Committee (NGAC) will meet on December 3, 2014, from 1:00 p.m. to 4:00 p.m. EST. The meeting will be held via web conference and teleconference.

The NGAC, which is composed of representatives from governmental, private sector, non-profit, and academic organizations, has been established to advise the Chair of the Federal Geographic Data Committee on management of Federal geospatial programs, the development of the National Spatial Data Infrastructure, and the implementation of Office of Management and Budget (OMB) Circular A-16. Topics to be addressed at the meeting include:

- FGDC Update
- Address Data
- Landsat Advisory Group
- Geospatial Privacy
- 2015 NGAC Activities

Members of the public who wish to attend the meeting must register in advance. Please register by contacting Lucia Foulkes at the Federal Geographic Data Committee (703-648-4142, lfoulkes@usgs.gov). Meeting registrations are due by November 28, 2014. Meeting information (web conference and teleconference instructions) will be provided to registrants prior to the meeting. While the meeting will be open to the public, attendance may be limited due to web conference and teleconference capacity.

The meeting will include an opportunity for public comment. Attendees wishing to provide public comment should register by November 28. Please register by contacting Lucia Foulkes at the Federal Geographic Data Committee (703-648-4142, lfoulkes@usgs.gov). Comments may also be submitted to the NGAC in writing.

DATES: The meeting will be held on December 3, 2014, from 1:00 p.m. to 4:00 p.m. EST.

FOR FURTHER INFORMATION CONTACT: John Mahoney, U.S. Geological Survey (206-220-4621).

SUPPLEMENTARY INFORMATION: Meetings of the National Geospatial Advisory Committee are open to the public. Additional information about the NGAC and the meeting are available at www.fgdc.gov/ngac.

Kenneth Shaffer,

Deputy Executive Director, Federal Geographic Data Committee.

[FR Doc. 2014-26863 Filed 11-12-14; 8:45 am]

BILLING CODE 4311-AM-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[15X.LLID9570000. L14200000.BJ0000.241A.4500074039]

Idaho: Filing of Plats of Survey

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of surveys.

SUMMARY: The Bureau of Land Management (BLM) has officially filed the plats of survey of the lands described below in the BLM Idaho State Office, Boise, Idaho, effective 9:00 a.m., on the dates specified.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, 1387 South Vinnell Way, Boise, Idaho 83709-1657.

SUPPLEMENTARY INFORMATION: These surveys were executed at the request of the Bureau of Land Management to meet their administrative needs. The lands surveyed are:

The field notes representing the remonumentation of certain original corners and monumentation of certain angle points of the Little Jacks Creek Wilderness boundary in T. 8 S., R. 1 E., Boise Meridian, Idaho, Group Number 1317, was approved July 25, 2014.

The field notes representing the remonumentation of certain original corners and monumentation of certain angle points of the Little Jacks Creek Wilderness boundary and Big Jacks

Creek Wilderness Area 1 boundary in T. 8 S., R. 3 E., Boise Meridian, Idaho, Group Number 1317, was approved July 25, 2014.

The field notes representing the remonumentation of certain original corners and monumentation of certain angle points of the Big Jacks Creek Wilderness Area 1 boundary in T. 8 S., R. 4 E., Boise Meridian, Idaho, Group Number 1317, was approved July 25, 2014.

The field notes representing the remonumentation of certain original corners and monumentation of certain angle points of the Little Jacks Creek Wilderness boundary in T. 9 S., R. 2 E., Boise Meridian, Idaho, Group Number 1317, was approved July 25, 2014.

The field notes representing the remonumentation of certain original corners and monumentation of certain angle points of the Little Jacks Creek Wilderness boundary and Big Jacks Creek Wilderness Area 1 boundary in T. 9 S., R. 3 E., Boise Meridian, Idaho, Group Number 1317, was approved July 25, 2014.

The field notes representing the remonumentation of certain original corners and monumentation of certain angle points of the Big Jacks Creek Wilderness Area 1 boundary in T. 9 S., R. 4 E., Boise Meridian, Idaho, Group Number 1317, was approved July 25, 2014.

The field notes representing the remonumentation of certain original corners and monumentation of certain angle points of the Big Jacks Creek Wilderness Area 1 boundary in T. 10 S., R. 2 E., Boise Meridian, Idaho, Group Number 1317, was approved July 25, 2014.

The field notes representing the remonumentation of certain original corners and monumentation of certain angle points of the Big Jacks Creek Wilderness Area 1 boundary in T. 10 S., R. 3 E., Boise Meridian, Idaho, Group Number 1317, was approved July 25, 2014.

The plat constituting the entire survey record of the dependent resurvey of a portion of the west boundary, T. 10 S., R. 3 E., Boise Meridian, Idaho, Group Number 1317, was accepted July 25, 2014.

The field notes representing the remonumentation of certain original corners and monumentation of certain angle points of the Big Jacks Creek Wilderness Area 2 boundary in T. 11 S., R. 3 E., Boise Meridian, Idaho, Group Number 1317, was approved July 25, 2014.

The plat constituting the entire survey record of the dependent resurvey of portions of the east boundary and

subdivisional lines, and the subdivision of sec. 24, T. 11 S., R. 3 E., Boise Meridian, Idaho, Group Number 1317, was accepted July 25, 2014.

The field notes representing the remonumentation of certain original corners and monumentation of certain angle points of the Big Jacks Creek Wilderness Area 2 boundary in T. 11 S., R. 4 E., Boise Meridian, Idaho, Group Number 1317, was approved July 25, 2014.

The supplemental plat showing new lots 1 and 2 in sec. 12, T. 8 N., R. 5 W., Boise Meridian, Idaho, Group Number 1424, was accepted September 5, 2014.

The supplemental plat portraying lot 7, T. 4 S., R. 36 E., Boise Meridian, Idaho, Group Number 1316, was accepted September 5, 2014.

These surveys were executed at the request of the U.S.D.A. Natural Resources Conservation Service to meet their administrative needs. The lands surveyed are:

The plat representing the dependent resurvey of portions of the First Standard Parallel North (north boundary) and subdivisional lines, and the subdivision of section 4, and a metes-and-bounds survey in section 4, T. 4 N., R. 24 E., of the Boise Meridian, Idaho, Group Number 1397, was accepted August 27, 2014.

The plat representing the dependent resurvey of portions of the north boundary and subdivisional lines, and the subdivision of sections 4, 9, 10, 13, 14, 15, and 23, T. 2 N., R. 24 E., of the Boise Meridian, Idaho, Group Number 1396, was accepted September 25, 2014.

The plat represents the dependent resurvey of portions of the First Standard Parallel North (south boundary), west boundary, and subdivisional lines, and the subdivision of sections 30 and 31, and a metes-and-bounds survey in sections 30 and 31, T. 5 N., R. 24 E., of the Boise Meridian, Idaho, Group Number 1398, was accepted September 25, 2014.

This survey was executed at the request of the U. S. Forest Service to meet certain administrative and management purposes.

The plat representing the dependent resurvey of a portion of Tract 39, and the survey of portions of the east boundary and subdivisional lines, T. 30 N., R. 7 E., of the Boise Meridian, Idaho, Group Number 1324, was accepted June 19, 2014.

Dated: October 30, 2014.

Stanley G. French,
Cadastral Surveyor for Idaho.

[FR Doc. 2014-26828 Filed 11-12-14; 8:45 am]

BILLING CODE 4310-GG-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-PWR-PWRO-13760;
PX.P0137227A.00.1]

Final Environmental Impact Statement for Cottonwood Cove and Katherine Landing Development Concept Plans, Lake Mead National Recreation Area, Arizona and Nevada

AGENCY: National Park Service, Interior.

ACTION: Notice of availability.

SUMMARY: The National Park Service announces availability of the Final Environmental Impact Statement (EIS) for the Cottonwood Cove and Katherine Landing Development Concept Plans, Lake Mead National Recreation Area. The document describes and analyzes three alternatives. *Alternative 1* (no action alternative) reflects current management direction and serves as a baseline for comparison with the other alternatives. Existing facilities would be retained with minimal changes. *Alternative 2 Implement Previous Planning Proposals* would implement previous planning proposals that separate day use and marina facilities, maintain the type of overnight facilities, and provide flood mitigation. *Alternative 3 Enhance Visitor Experience and Park Operations* (agency-preferred alternative) would enhance day-use opportunities, upgrade and expand the type of overnight facilities, and provide flood mitigation. The Final EIS also analyzes the potential environmental impacts of the alternatives, including: Potential impacts to native plant communities and soils; wildlife; threatened, endangered, and special status species; floodplains; archeological resources; historic structures; cultural landscape; ethnographic resources; visitor use, experience, and safety; park operations; and socioeconomic environment.

DATES: The Record of Decision for the Cottonwood Cove and Katherine Landing Development Concept Plans will be executed not sooner than 30 days after the date of publication by the Environmental Protection Agency of its notice of filing of the Final EIS in the **Federal Register**.

ADDRESSES: The Final EIS is available for public inspection at <http://parkplanning.nps.gov.lake>, and in the office of the Superintendent, Lake Mead National Recreation Area, 601 Nevada Way, Boulder City, NV 89005, (702) 293-8920.

FOR FURTHER INFORMATION CONTACT: Mr. Jim Holland, Park Planner, Lake Mead

National Recreation Area, 601 Nevada Highway, Boulder City, NV 89005, (702) 293-8986.

SUPPLEMENTARY INFORMATION: The purposes of the development concept plans are to reevaluate the implementation strategies for these two areas that were identified in the 1986 *Lake Mead National Recreation Area General Management Plan/Development Concept Plans/Final Environmental Impact Statement* (GMP), and to incorporate the concepts and carrying capacities that were approved in the 2003 *Lake Mead National Recreation Area Lake Management Plan/Final Environmental Impact Statement* (LMP). Each development concept plan provides an integrated plan for development with site-specific guidance for the extent, type, and location of facilities and services that is consistent with the management direction and intent established in the GMP and the LMP.

The GMP addressed the need to provide recreational opportunities while preserving and protecting natural and cultural resources. It established land-based management zones and included development concept plans for Cottonwood Cove and Katherine Landing that identified limits on the development, established the number and type of facilities, and addressed flood hazards. The GMP's vision for both areas was to accommodate increasing use, enhance the visitor experience, and mitigate flood hazards. The LMP established water-based management zones and provided further guidance for the long-term protection of park resources while allowing a range of recreational opportunities to support visitor needs. A number of the management actions identified in both approved plans require more site-specific development planning. There are also a number of management issues that have not been adequately addressed or resolved in the previous planning efforts and that require a more detailed examination of development and operational needs. The primary issues addressed in the Final EIS are as follows: (1) Water quality and flood control; (2) air quality; (3) socioeconomics guiding policies, regulations, and laws; and (4) Park operations methodologies and assumptions.

Decision Process: Not sooner than 30 days after the publication of the Environmental Protection Agency's notice of filing of the Final EIS in the **Federal Register**, a Record of Decision will be executed. As a delegated EIS, the official responsible for approval of the

Cottonwood Cove and Katherine Landing Development Concept Plans is the NPS Regional Director, Pacific West Region. Subsequently the official responsible for project implementation and for monitoring results is the Superintendent, Lake Mead National Recreation Area.

Dated: September 17, 2014.

Patricia L. Neubacher,

Acting Regional Director, Pacific West Region.

[FR Doc. 2014-26824 Filed 11-12-14; 8:45 am]

BILLING CODE 4312-FF-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-NCR-WHHA-17124; PPNCWHHA1, PPMSPD1Z.YM0000]

Notice of Meeting, Committee for the Preservation of the White House

AGENCY: National Park Service, Interior.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given in accordance with the Federal Advisory Committee Act (5 U.S.C. Appendix 1-16) that a meeting of the Committee for the Preservation of the White House will be held at the White House at 12:00 p.m. on Thursday, December 11, 2014.

DATES: Thursday, December 11, 2014 (Eastern).

ADDRESSES: The White House, 1600 Pennsylvania Avenue NW., Washington, DC 20500.

FOR FURTHER INFORMATION CONTACT:

Comments may be provided to: John Stanwich, Executive Secretary, Committee for the Preservation of the White House, 1100 Ohio Drive SW., Washington, DC 20242, (202) 619-6344. Before including your address, telephone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

SUPPLEMENTARY INFORMATION: It is expected that the meeting agenda will include policies, goals, and long-range plans. The meeting will be open, but subject to appointment and security clearance requirements. Clearance information, which includes full name, date of birth, Social Security number, city and state of residence, and country of citizenship must be received by December 3, 2014. Due to the present

mail delays being experienced, clearance information should be faxed to (202) 619-6353 in order to assure receipt by deadline. Inquiries may be made by calling the Committee for the Preservation of the White House between 9 a.m. and 4 p.m. weekdays at (202) 619-6344. Written comments may be sent to John Stanwich, Executive Secretary, Committee for the Preservation of the White House, 1100 Ohio Drive SW., Washington, DC 20242.

Dated: November 6, 2014.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2014-26923 Filed 11-12-14; 8:45 am]

BILLING CODE 4310-EE-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-NER-BOHA-17092; PPMSPD1Z.YM0000] [PPNEBOHAS1]

Boston Harbor Islands National Recreation Area Advisory Council

AGENCY: National Park Service, Interior.

ACTION: Notice of meeting.

SUMMARY: This notice announces a meeting of the Boston Harbor Islands National Recreation Area Advisory Council. The agenda includes a presentation by Cathy Stanton, anthropologist, lecturer, and writer who has been investigating the origins of the cottages located on Peddocks Island and is exploring whether this area can be classified as a “community” within the Boston Harbor Islands. There will also be a discussion about the Council’s mission, goals, and community outreach initiative, and Superintendent Giles Parker will give updates about park operations and planning efforts.

DATES: December 10, 2014, 4:00 p.m. to 6:00 p.m. (EASTERN).

ADDRESSES: WilmerHale, 60 State Street, 26th Floor Conference Room, Boston, MA 02109.

FOR FURTHER INFORMATION CONTACT:

Giles Parker, Superintendent and Designated Federal Officer (DFO), Boston Harbor Islands National Recreation Area, 15 State Street, Suite 1100, Boston, MA 02109, telephone (617) 223-8669, or email giles_parker@nps.gov.

SUPPLEMENTARY INFORMATION: This meeting open to the public. Those wishing to submit written comments may contact the DFO for the Boston Harbor Islands National Recreation Area Advisory Council, Giles Parker, by mail at National Park Service, Boston Harbor Islands, 15 State Street, Suite 1100,

Boston, MA 02109, or via email giles_parker@nps.gov. Before including your address, telephone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

The Council was appointed by the Director of the National Park Service pursuant to 16 U.S.C. 460kkk(g). The purpose of the Council is to advise and make recommendations to the Boston Harbor Islands Partnership with respect to the implementation of a management plan and park operations. Efforts have been made locally to ensure that the interested public is aware of the meeting dates.

Dated: November 7, 2014.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2014-26921 Filed 11-12-14; 8:45 am]

BILLING CODE 4310-EE-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-888]

Certain Silicon Microphone Packages and Products Containing Same; Commission Determination To Review in Part a Final Initial Determination; Schedule for Filing Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review in part the final initial determination (“ID”) issued by the presiding administrative law judge (“ALJ”) finding a violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337) (“section 337”), in the above-referenced investigation on August 29, 2014.

FOR FURTHER INFORMATION CONTACT: Michael Liberman, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205-3115. Copies of non-confidential documents filed in connection with this investigation are or will be available for

inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server at <http://www.usitc.gov>. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <http://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on July 26, 2013, based on a complaint filed by Knowles Electronics, LLC, of Itasca, Illinois. 78 FR 45272 (July 26, 2013). The notice of investigation named GoerTek, Inc. of Weifang, China and GoerTek Electronics, Inc. of Sunnyvale, California as respondents. The Commission's Office of Unfair Import Investigations is not a party to this investigation. The complaint alleged violations of section 337 in the importation into the United States, the sale for importation, and the sale within the United States after importation of silicon microphone packages and products containing the same, by reason of infringement of certain claims of U.S. Patent Nos. 7,439,616 ("the '616 patent"); 8,018,049 ("the '049 patent"); and 8,121,331 ("the '331 patent"). Subsequently, the investigation was terminated as to claims 13 and 14 of the '616 patent and claim 24 of the '049 patent based on the withdrawal of complainant's allegations as to those claims. See Notice (May 16, 2014) (determining not to review Order No. 37 issued on April 17, 2014).

The final ID on violation was issued on August 29, 2014. The ALJ issued his recommended determination ("RD") on remedy, the public interest and bonding on the same day. The ALJ found that a violation of section 337 has occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain silicon microphone packages and products containing same, by reason of infringement of one or more of claims 1, 2, 8, 11-12, 15-18, and 21 of the '616 patent; claims 1, 15, 16, 19, 21-23, and 25-26 of the '049 patent; and claims 1, 2, 4, 5, and 11-13 of the '331 patent. The ALJ recommended that the Commission issue a limited exclusion order directed to respondents' accused products that infringe the '616, '049,

and '331 patents. The ALJ did not recommend issuance of a cease and desist order against respondents.

On October 2, 2014, complainant filed a post-RD statement on the public interest pursuant to Commission Rule 201.50(a)(4). No responses from the public were received in response to the post-RD Commission Notice issued on September 3, 2014. See Notice of Request for Statements on the Public Interest (Sep. 3, 2014).

Having examined the record in this investigation, including the ALJ's final ID, the petitions for review, and the responses thereto, the Commission has determined to review the ID in part. In particular, the Commission has determined to review the construction of the "cover" limitation with respect to the '616 and '049 patent as well as related anticipation, obviousness, infringement and technical prong analyses. In addition, the Commission has determined to review infringement with respect to claim 8 of the '616 patent.

The parties are requested to brief their positions on only the following issues, with reference to the applicable law and the evidentiary record:

(1) Please discuss whether the record supports or precludes the ALJ's interpretation of the claim limitations "the at least one layer of conductive material in the cover" and "conductive layer formed in the cover" in the '049 and '616 patents, respectively. As part of this discussion, please address:

(a) Whether the references to "a shield to protect . . . against electromagnetic interference" in claim 1 of the '049 patent and "a shield against electromagnetic interference" in claims 11 and 15 of the '616 patent provide context for interpreting the above-mentioned claim limitations; and

(b) Whether multiple layers in the cover are relevant in order to provide "a shield to protect" or "a shield against" electromagnetic interference.

(2) With respect to the '049 and '616 patents, please discuss, in light of your response to the Commission's question pertaining to construction of claim limitations "the at least one layer of conductive material in the cover" and "conductive layer formed in the cover" in the '049 and '616 patents, respectively, whether the record supports the ALJ's findings regarding these limitations with respect to infringement, technical prong, and non-obviousness, including the evidence of secondary considerations of non-obviousness.

(3) Assuming the asserted claims of the '049 patent require the presence of one or more additional layers in the

cover besides "at least one layer of conductive material," how does the presence of that additional material impact the respondents' allegation that the asserted claims are obvious in light of Halteren and Une under *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007)? Please provide support and citations to the evidentiary record.

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more cease and desist orders that could result in the respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or are likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843 (Dec. 1994) (Commission Opinion).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. See Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury.

Written Submissions: The parties to the investigation are requested to file written submissions on the issues

identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest and bonding. Such submissions should address the recommended determination on remedy, the public interest and bonding issued on August 29, 2014, by the ALJ. Complainant is also requested to submit proposed remedial orders for the Commission's consideration and to provide identification information for all importers of the subject articles. Complainant is further requested to provide the expiration dates of the '616, '049, and '331 patents and state the HTSUS numbers under which the accused articles are imported. The written submissions and proposed remedial orders must be filed no later than the close of business on November 20, 2014. Reply submissions must be filed no later than the close of business on December 1, 2014. No further submissions on these issues will be permitted unless otherwise ordered by the Commission. Party submissions should not exceed 50 pages for the main submissions and 25 pages for the reply submissions.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-888") in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf). Persons with questions regarding filing should contact the Secretary (202-205-2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with the confidential filing. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: November 06, 2014.

Lisa R. Barton,

Secretary for the Commission.

[FR Doc. 2014-26804 Filed 11-12-14; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On November 6, 2014, the Department of Justice lodged a proposed consent decree with the United States District Court for the Middle District of Louisiana in the lawsuit entitled *United States and the Louisiana Department of Environmental Quality v. PCS Nitrogen Fertilizer, L.P., AA Sulfuric, Inc., and White Springs Agricultural Chemicals, Inc.*, Civil Action No. 3:14-cv-00707.

The United States and Louisiana Department of Environmental Quality filed this lawsuit under the Clean Air Act and Louisiana Environmental Quality Act. The complaint seeks injunctive relief and civil penalties for violations of the Clean Air Act's Prevention of Significant Deterioration requirements and related state requirements at sulfuric acid manufacturing plants owned and operated by the defendants, PCS Nitrogen Fertilizer, L.P., AA Sulfuric, Inc., and White Springs Agricultural Chemicals, Inc., in Geismar, Louisiana and White Springs, Florida. The consent decree requires the defendants to perform injunctive relief, pay a \$ 1,300,000 civil penalty, and perform a Supplemental Environmental Project at a nitric acid manufacturing facility owned and operated by PCS Nitrogen Fertilizer, Inc. in Geismar, Louisiana. The consent decree also requires PCS Phosphate Company, Inc. to perform injunctive relief at the sulfuric acid manufacturing facility that it owns and operates in Aurora, North Carolina.

The publication of this notice opens a period for public comment on the proposed consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and the Louisiana Department of Environmental Quality v. PCS Nitrogen Fertilizer, L.P. et al.*, D.J.

Ref. No. 90-7-1-08209/1. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

<i>To submit comments:</i>	<i>Send them to:</i>
By e-mail	pubcomment-ees.enrd@usdoj.gov .
By mail	Assistant Attorney General U.S. DOJ—ENRD P.O. Box 7611 Washington, D.C. 20044–7611.

During the public comment period, the proposed consent decree may be examined and downloaded at this Justice Department Web site: <http://www.usdoj.gov/enrd/ConsentDecrees.html>. We will provide a paper copy of the proposed consent decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044-7611.

Please enclose a check or money order for \$43.50 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy without the exhibits and signature pages, the cost is \$ 17.00.

Maureen M. Katz,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2014-26847 Filed 11-12-14; 8:45 am]

BILLING CODE 4410-15-P

DEPARTMENT OF JUSTICE

Antitrust Division

United States v. Media General, Inc. and Lin Media LLC; Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), that a proposed Final Judgment, Asset Preservation Stipulation, and Competitive Impact Statement have been filed with the United States District Court for the District of Columbia in *United States of America v. Media General, Inc. and LIN Media LLC*, Civil Action No. CV-14-01823. On October 30, 2014, the United States filed a Complaint alleging that the proposed acquisition by Media General, Inc. of LIN Media LLC would likely substantially lessen competition for broadcast television spot advertising in certain Designated Market Areas (DMAs) in the United States, in

violation of Section 7 of the Clayton Act, 15 U.S.C. 18. The proposed Final Judgment, filed on the same day as the Complaint, resolves the case by requiring Media General to divest WVTM-TV(NBC), located in the Birmingham, Alabama DMA; WJCL (ABC) and WTGS (FOX), both located in the Savannah, Georgia DMA; WALA-TV (FOX), located in the Mobile, Alabama/Pensacola, Florida DMA; WJAR (NBC), located in the Providence, Rhode Island/New Bedford, Massachusetts DMA; and WLUK-TV(FOX) and WCWF (CW), both located in the Green Bay/Appleton, Wisconsin DMA. A Competitive Impact Statement filed by the United States describes the Complaint, the proposed Final Judgment, and the industry.

Copies of the Complaint, proposed Final Judgment, and Competitive Impact Statement are available for inspection at the Department of Justice, Antitrust Division, Antitrust Documents Group, 450 Fifth Street NW., Suite 1010, Washington, DC 20530 (telephone: 202-514-2481), on the Department of Justice's Web site at <http://www.usdoj.gov/atr>, and at the Office of the Clerk of the United States District Court for the District of Columbia. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Public comment is invited within 60 days of the date of this notice. Such comments, including the name of the submitter, and responses thereto, will be posted on the U.S. Department of Justice, Antitrust Division's internet Web site, filed with the Court and, under certain circumstances, published in the **Federal Register** and filed with the Court. Comments should be directed to David Kully, Chief, Litigation III, Antitrust Division, Department of Justice, Washington, DC 20530, (telephone: 202-305-9969).

Patricia A. Brink,
Director of Civil Enforcement.

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

United States of America, Department of Justice, Antitrust Division, 450 Fifth Street NW., Suite 4000, Washington, DC 20530, Plaintiff, v. Media General, Inc., 333 E. Franklin Street, Richmond, VA 23219 and LIN Media LLC, 701 Brazos Street, Suite 800, Austin, TX 78701, Defendants.

Case No. 1:14-cv-01823
Judge: Hon. Emmet G. Sullivan
Filed: 10/30/2014

Complaint

The United States of America, acting under the direction of the Attorney General of the United States brings this civil action to enjoin the proposed acquisition by Media General, Inc. ("Media General") of LIN Media LLC ("LIN") (collectively, "Defendants") and to obtain other equitable relief. The proposed acquisition likely would substantially lessen competition in the sale of broadcast television spot advertising in the following Designated Market Areas ("DMAs"): Mobile, Alabama/Pensacola, Florida; Birmingham, Alabama; Savannah, Georgia; Providence, Rhode Island/New Bedford, Massachusetts; and Green Bay/Appleton, Wisconsin (collectively "the DMA Markets"), in violation of Section 7 of the Clayton Act, 15 U.S.C. 18. Plaintiff alleges as follows:

I. Nature of the Action

1. Pursuant to a Purchase Agreement dated March 21, 2014, Media General agreed to purchase LIN whereby LIN shareholders would receive aggregate consideration valued at approximately \$1.5 billion in a combination of stock and cash.

2. Media General and LIN both own and operate broadcast television stations in each of the DMA Markets. Media General's and LIN's broadcast television stations compete head-to-head for the business of local and national companies that advertise on broadcast television stations in each of the DMA Markets.

3. If consummated, the proposed acquisition would eliminate the head-to-head competition between Media General and LIN in each of the DMA Markets. Unless enjoined, the acquisition is likely to lead to higher prices and will substantially lessen competition for broadcast television spot advertising in each of the DMA Markets in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.

II. Jurisdiction and Venue

4. The United States brings this action pursuant to Section 15 of the Clayton Act, as amended, 15 U.S.C. 25, to prevent and restrain Defendants from violating Section 7 of the Clayton Act, 15 U.S.C. 18.

5. Defendants sell broadcast television spot advertising, a commercial activity that substantially affects, and is in the flow of, interstate commerce. The Court has subject-matter jurisdiction over this action pursuant to Section 15 of the Clayton Act, 15 U.S.C. 25, and 28 U.S.C. 1331, 1337(a), and 1345.

6. Defendants transact business and are found in the District of Columbia,

and are subject to the personal jurisdiction of this Court. Defendants have consented to venue and personal jurisdiction in this District. Therefore, venue is proper in this District under Section 12 of the Clayton Act, 15 U.S.C. 22, and 28 U.S.C. 1391(c).

III. The Defendants

7. Media General is incorporated in the Commonwealth of Virginia, with its headquarters in Richmond, Virginia. Media General reported operating revenues of over \$270 million in 2013. Media General owns and operates 31 broadcast television stations in 29 metropolitan areas. It owns and operates broadcast television stations in each of the DMA Markets.

8. LIN is a Delaware corporation, with its headquarters in Austin, Texas. LIN owns and operates, or provides programming, operating, or sales services to more than 50 stations in 23 metropolitan areas. It also owns and operates, or provides programming, operating, or sales services to broadcast television stations in each of the DMA Markets.

IV. Trade and Commerce

A. Broadcast Television Spot Advertising Is a Relevant Product Market

9. Broadcast television stations attract viewers through their programming, which is delivered for free over the air or retransmitted to viewers, mainly through wired cable or other terrestrial television systems and through satellite television systems. Broadcast television stations then sell advertising time to businesses that want to advertise their products to television viewers. Broadcast television "spot" advertising, which comprises the majority of a television station's revenues, is sold directly by the station itself or through its national representative on a localized basis and is purchased by advertisers who want to target potential customers in specific geographic areas. Spot advertising differs from network and syndicated television advertising, which are sold by television networks and producers of syndicated programs on a nationwide basis and broadcast in every market where the network or syndicated program is aired.

10. Broadcast television spot advertising possesses a unique combination of attributes that set it apart from advertising using other types of media. Television combines sight, sound, and motion, thereby creating a more memorable advertisement. Moreover, of all media, broadcast television spot advertising generally

reaches the largest percentage of all potential customers in a particular target geographic area and is therefore especially effective in introducing, establishing, and maintaining the image of a product. For a significant number of advertisers, broadcast television spot advertising, because of its unique combination of attributes, is an advertising medium for which there is no close substitute. Other media, such as radio, newspapers, or outdoor billboards, are not desirable substitutes for broadcast television advertising. None of these media can provide the important combination of sight, sound, and motion that makes television unique and impactful as a medium for advertising.

11. Like broadcast television, subscription television channels, such as those carried over cable or satellite television, combine elements of sight, sound, and motion, but they are not a desirable substitute for broadcast television spot advertising for two important reasons. First, satellite, cable, and other subscription content delivery systems do not have the “reach” of broadcast television. Typically, broadcast television can reach well-over 90% of homes in a DMA, while cable television often reaches many fewer homes. Even when several subscription television companies within a DMA jointly offer cable television spot advertising through a consortium called an interconnect, cable spot advertising does not match the reach of broadcast television spot advertising. As a result, an advertiser can achieve greater audience penetration through broadcast television spot advertising than through advertising on a subscription television channel. Second, because subscription services may offer more than 100 channels, they fragment the audience into small demographic segments. Because broadcast television programming typically has higher rating points than subscription television programming, broadcast television provides a much easier and more efficient means for an advertiser to reach a high proportion of its target demographic. Media buyers often buy time on subscription television channels not so much as a substitute for broadcast television, but rather to supplement a broadcast television message, to reach a narrow demographic (e.g., 18–24 year olds) with greater frequency, or to target narrow geographic areas within a DMA. A small but significant price increase by broadcast television spot advertising providers would not be made unprofitable by advertisers switching to

advertising on subscription television channels.

12. Internet-based media is not currently a substitute for broadcast television spot advertising. Although Online Video Distributors (“OVDs”) such as Netflix and Hulu are important sources of video programming, as with cable television advertising, the local video advertising of OVDs lacks the reach of broadcast television spot advertising. Non-video internet advertising, e.g., Web site banner advertising, lacks the important combination of sight, sound, and motion that gives television its impact. Consequently, local media buyers currently purchase internet-based advertising primarily as a supplement to broadcast television spot advertising, and a small but significant price increase by broadcast television spot advertising providers would not be made unprofitable by advertisers switching to internet-based advertising.

13. Broadcast television stations generally can identify advertisers with strong preferences for using broadcast television advertising. Broadcast television stations negotiate prices individually with advertisers and consequently can charge different advertisers different prices. During the individualized negotiations on price and available advertising slots that commonly occur between advertisers and broadcast television stations, advertisers provide stations with information about their advertising needs, including their target audience. Broadcast television stations could profitably raise prices to those advertisers who view broadcast television as a necessary advertising medium, either as their sole means of advertising or as a necessary part of a total advertising plan.

14. Accordingly, the sale of broadcast television spot advertising is a line of commerce under Section 7 of the Clayton Act and a relevant product market for purposes of analyzing the proposed acquisition under Section 7 of the Clayton Act.

B. Each of the Divestiture Markets Is a Relevant Geographic Market

15. DMAs are geographic units defined by the A.C. Nielsen Company, a firm that surveys television viewers and furnishes broadcast television stations, advertisers, and advertising agencies in a particular area with data to aid in evaluating audience size and composition. DMAs are ranked according to the number of households they contain. Signals from broadcast television stations located in a DMA Market reach viewers located

throughout the DMA, but signals from broadcast television stations located outside the DMA reach few viewers within the DMA. DMAs are used to analyze revenues and shares of broadcast television stations in the *Investing in Television BIA Market Report 2014* (1st edition), a standard industry reference.

16. Advertisers use broadcast television stations within each of the DMA Markets to reach the largest possible number of viewers across the DMA. Some of these advertisers are located in each of the DMA Markets and need to reach customers there; others are regional or national businesses that want to target consumers across each of the DMA Markets. Advertising on television stations outside each of the DMA Markets is not an alternative for these advertisers because such stations cannot be viewed by a significant number of potential customers within each of the DMAs. Thus, if there were a small but significant increase in broadcast television spot advertising prices within a specific DMA Market, an insufficient number of advertisers would switch advertising purchases to television stations outside that DMA to render the price increase unprofitable.

17. Accordingly, each of the DMA Markets is a section of the country under Section 7 of the Clayton Act and a relevant geographic market for the sale of broadcast television spot advertising for purposes of analyzing the proposed acquisition under Section 7 of the Clayton Act.

C. The Proposed Acquisition Would Harm Competition in Each of the DMA Markets

18. Broadcast television stations compete for advertisers through programming that attracts viewers to their stations. In developing their own programming and in considering the programming of the networks with which they may be affiliated, broadcast television stations try to select programs that appeal to the greatest number of viewers and to differentiate their stations from others in the same DMA by appealing to specific demographic groups. Advertisers, in turn, are interested in using broadcast television spot advertising to reach both a large audience and a high proportion of the type of viewers that are most likely to buy their products.

19. Broadcast station ownership in each of the DMA Markets is already significantly concentrated. In each of these markets, four stations, each affiliated with a major network, had more than 90 percent of gross advertising revenues in 2013. In the

Mobile, Alabama/Pensacola, Florida DMA, the three stations that Media General and LIN operate have approximately 54 percent of all television station gross advertising revenues in that DMA. In the Birmingham, Alabama DMA, the two stations that Media General and LIN operate have approximately 34 percent of all television station gross advertising revenues in that DMA. In the Savannah, Georgia DMA, the three stations that Media General and LIN operate have approximately 55 percent of all television station gross advertising revenues in that DMA. In the Providence, Rhode Island/New Bedford, Massachusetts DMA, the three stations that Media General and LIN operate have approximately 83 percent of all television station gross advertising revenues in that DMA. In the Green Bay/Appleton, Wisconsin DMA, the three stations that Media General and LIN operate have approximately 59 percent of all television station gross advertising revenues in that DMA.

20. Using the Herfindahl-Hirschman Index (“HHI”), a standard measure of market concentration (defined and explained in Appendix A), a combination of Media General’s and LIN’s broadcast television stations in each of the DMA markets would result in both a large change in concentration and a highly concentrated market. The post-acquisition HHI in each of the DMA Markets would be over 2500 with an increase in the HHI of more than 500 points. Under the Horizontal Merger Guidelines issued by the Department of Justice and the Federal Trade Commission, mergers resulting in highly concentrated markets (with an HHI in excess of 2500) and with an increase in the HHI of more than 200 points are presumed to be likely to enhance market power.

21. In addition to increasing concentration in the DMA Markets, the proposed transaction combines stations that are close substitutes and vigorous competitors in markets with limited alternatives. In each of the DMA Markets, Defendants have broadcast stations that are affiliated with the major national television networks, ABC, CBS, NBC, and FOX. Their respective affiliations with those networks, and their local news operations, provide Defendants’ stations with a variety of competing programming options that are often each other’s next-best or second-best substitutes for many viewers and advertisers.

22. Advertisers benefit from Defendants’ head-to-head competition in the sale of broadcast television spot advertising in each of the DMA Markets.

Advertisers purposefully spread their advertising dollars across numerous spot advertising suppliers to reach their marketing goals most efficiently. After the proposed acquisition, advertisers in each of the DMA Markets would likely find it more difficult to “buy around” the Defendants’ combined stations in response to higher advertising rates, than to “buy around” Media General’s stations or LIN’s stations, as separate entities, as they could have done before the proposed acquisition. Because a significant number of advertisers would likely be unable to reach their desired audiences as effectively unless they advertise on at least one station that Media General would control after the proposed acquisition, those advertisers’ bargaining positions would be weaker, and the advertising rates they pay would likely increase.

23. Accordingly, the proposed acquisition is likely to substantially reduce competition and will restrain trade in the sale of broadcast television spot advertising in each of the DMA Markets.

D. Lack of Countervailing Factors

1. Entry and Expansion Are Unlikely

24. De novo entry into each of the DMA Markets is unlikely. The FCC regulates entry through the issuance of broadcast television licenses, which are difficult to obtain because the availability of spectrum is limited and the regulatory process associated with obtaining a license is lengthy. Even if a new signal became available, commercial success would come, at best, over a period of many years. In each of the DMA Markets, all of the major broadcast networks (CBS, NBC, ABC, FOX) are already affiliated with a licensee, the contracts last for many years, and the broadcast networks rarely switch licensees when the contracts expire. Thus, entry into each DMA Market’s broadcast television spot advertising market would not be timely, likely, or sufficient to deter Media General from engaging in anticompetitive price increases or other anticompetitive conduct after the proposed acquisition occurs.

25. Other broadcast television stations in each of the DMA Markets could not readily increase their advertising capacity or change their programming sufficiently in response to a price increase by Defendants. The number of 30-second spots in a DMA is largely fixed by programming and time constraints. This fact makes the pricing of spots very responsive to changes in demand. During so-called political years, for example, political

advertisements crowd out commercial advertising and make the spots available for commercial advertisers more expensive than they would be in nonpolitical years. Adjusting programming in response to a pricing change is risky, difficult, and time-consuming. Network affiliates are often committed to the programming provided by the network with which they are affiliated, and it often takes years for a station to build its audience. Programming schedules are complex and carefully constructed, taking many factors into account, such as audience flow, station identity, and program popularity. In addition, stations typically have multi-year contractual commitments for individual shows. Accordingly, a television station is unlikely to change its programming sufficiently or with sufficient rapidity to overcome a small but significant price increase imposed by Defendants.

2. The Alleged Efficiencies Do Not Offset the Harm

26. Although Defendants assert that the proposed acquisition would produce efficiencies, they cannot demonstrate acquisition-specific and cognizable efficiencies that would be sufficient to offset the proposed acquisition’s anticompetitive effects.

V. Violations Alleged

27. Plaintiff hereby repeats and realleges the allegations of paragraphs 1 through 26 as if fully set forth herein.

28. The proposed acquisition likely would lessen competition substantially in interstate trade and commerce, in violation of Section 7 of the Clayton Act, 15 U.S.C. 18. The proposed acquisition likely would have the following effects, among others:

a. Competition in the sale of broadcast television spot advertising in each of the DMA Markets would be lessened substantially;

b. competition among Media General and LIN in the sale of broadcast television spot advertising in each of the DMA Markets would be eliminated; and

c. the prices for spot advertising time on broadcast television stations in each of the DMA Markets would likely increase.

29. Unless restrained, the proposed acquisition would violate Section 7 of the Clayton Act, 15 U.S.C. 18.

VI. Request for Relief

30. Plaintiff requests:

d. That the Court adjudge the proposed merger to violate Section 7 of the Clayton Act, 15 U.S.C. 18;

e. that the Court permanently enjoin and restrain Defendants from carrying

out the transaction, or entering into any other agreement, understanding, or plan by which Media General would acquire LIN, unless Defendants divest the broadcast television stations in accordance with the proposed Final Judgment and Hold Separate Stipulation and Order filed concurrently with this Complaint;

f. that the proposed Final Judgment giving effect to the divestitures be entered by the Court after compliance with the Antitrust Procedures and Penalties Act, 15 U.S.C. 16;

g. that the Court award Plaintiff the costs of this action; and

h. that the Court award such other relief to Plaintiff as the Court may deem just and proper.

Respectfully submitted,
For Plaintiff United States:

/s/
William J. Baer (D.C. Bar #324723)
Assistant Attorney General

/s/
David I. Gelfand (D.C. Bar #416596)
Deputy Assistant Attorney General

/s/
Patricia A. Brink
Director of Civil Enforcement

/s/
David C. Kully
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*Attorney of Record

Dated: October 30, 2014

Appendix A—Herfindahl-Hirschman Index

The term “HHI” means the Herfindahl-Hirschman Index, a commonly accepted measure of market concentration. The HHI is calculated by squaring the market share of each firm competing in the market and then summing the resulting numbers. For example, for a market consisting of four firms with shares of 30, 30, 20, and 20 percent, the HHI is 2,600 ($30^2 + 30^2 + 20^2 + 20^2 = 2,600$). The HHI takes into account the relative size distribution of the firms in a market. It approaches zero when a market is occupied by a large number of firms of relatively equal size and reaches its maximum of 10,000 points when a market is controlled by a single firm. The HHI increases both as the number of firms in the market decreases and as the disparity in size between those firms increases. Markets in which the HHI is between 1,500 and 2,500 points are considered to be moderately concentrated, and markets in which the HHI is in excess of 2,500 points are considered to be highly concentrated. See U.S. Department of Justice & FTC, *Horizontal Merger Guidelines* § 5.3

(2010). Transactions that increase the HHI by more than 200 points in highly concentrated markets presumptively raise antitrust concerns under the *Horizontal Merger Guidelines* issued by the Department of Justice and the Federal Trade Commission. See *id.*

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

United States of America, Plaintiff, v. Media General, Inc., and LIN Media LLC, Defendants.

Case No. 1:14-cv-01823
Judge: Hon. Emmet G. Sullivan
Filed: 10/30/2014

Competitive Impact Statement

Pursuant to Section 2(b) of the Antitrust Procedures and Penalties Act (“APPA” or “Tunney Act”), 15 U.S.C. 16(b)-(h), plaintiff United States of America (“United States”) files this Competitive Impact Statement relating to the proposed Final Judgment submitted for entry in this civil antitrust proceeding.

I. Nature and Purpose of the Proceeding

Defendants Media General, Inc. (“Media General”) and LIN Media LLC (“LIN”) entered into a Purchase Agreement, dated March 21, 2014, pursuant to which Media General would acquire LIN. Under the Purchase Agreement, LIN shareholders would receive approximately \$1.5 billion in a combination of stock and cash. Defendants compete head-to-head in the sale of broadcast television spot advertising in the following Designated Market Areas (“DMAs”): Mobile, Alabama/Pensacola, Florida; Birmingham, Alabama; Savannah, Georgia; Providence, Rhode Island/New Bedford, Massachusetts; and Green Bay/Appleton, Wisconsin (collectively “the DMA Markets”).

The United States filed a civil antitrust Complaint on October 30, 2014, seeking to enjoin the proposed acquisition. The Complaint alleges that the likely effect of the acquisition would be to lessen competition substantially and increase broadcast television spot advertising prices in each of the DMA Markets in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.

At the same time the Complaint was filed, the United States also filed a Hold Separate Stipulation and Order (“Hold Separate”) and proposed Final Judgment, which are designed to eliminate the anticompetitive effects of the proposed acquisition. Under the proposed Final Judgment, which is explained more fully below, Defendants are required to divest the Divestiture Assets (collectively, the “Divestiture

Stations”) to Acquirers approved by the United States in a manner that preserves competition in each of the DMA Markets: WVTM-TV, located in the Birmingham, Alabama DMA; WJCL and WTGS, both located in the Savannah, Georgia DMA; WALA-TV, located in the Mobile, Alabama/Pensacola, Florida DMA; WJAR, located in the Providence, Rhode Island/New Bedford, Massachusetts DMA; and WLUK-TV and WCWF, both located in the Green Bay/Appleton, Wisconsin DMA. The Hold Separate requires Defendants to take certain steps to ensure that the Divestiture Stations are operated as competitively independent, economically viable, and ongoing businesses that will remain independent and uninfluenced by the consummation of the acquisition that competition is maintained during the pendency of the ordered divestitures.

The United States and Defendants have stipulated that the proposed Final Judgment may be entered after compliance with the APPA. Entry of the proposed Final Judgment would terminate this action, except that the Court would retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgment and to punish violations thereof.

II. Description of the Events Giving Rise to the Alleged Violation

A. The Defendants and the Proposed Acquisition

Media General is incorporated in the Commonwealth of Virginia, with its headquarters in Richmond, Virginia. Media General owns and operates 31 broadcast television stations in 29 metropolitan areas. It owns and operates broadcast television stations in each of the DMA Markets.

LIN is a Delaware corporation, with its headquarters in Austin, Texas. LIN owns and operates, or provides programming, operating, or sales services to more than 50 stations in 23 metropolitan areas. It also owns and operates, or provides programming, operating, or sales services to broadcast television stations in each of the DMA Markets.

The proposed acquisition would lessen competition substantially in the sale of broadcast television spot advertising in each of the DMA Markets. This acquisition is the subject of the Complaint and proposed Final Judgment filed by the United States on October 30, 2014.

B. Anticompetitive Consequences of the Transaction

1. The Relevant Product

The Complaint alleges that the sale of broadcast television spot advertising constitutes a relevant product market for analyzing this acquisition under Section 7 of the Clayton Act. Television stations attract viewers through their programming and then sell advertising time to businesses wanting to advertise their products to those television viewers. Advertisers purchase broadcast television spot advertising to target potential customers in specific DMAs. Spot advertising differs from network and syndicated television advertising, which are sold on a nationwide basis by major television networks and by producers of syndicated programs and are broadcast in every market area in which the network or syndicated program is aired.

Broadcast television spot advertising possesses a unique combination of attributes that sets it apart from advertising using other types of media. Television combines sight, sound, and motion, thereby creating a more memorable advertisement. Broadcast television spot advertising generally reaches the largest percentage of potential customers in a targeted geographic area and is therefore especially effective in introducing, establishing, and maintaining a product's image.

Because of this unique combination of attributes, broadcast television spot advertising has no close substitute for a significant number of advertisers. Spot advertising on subscription television channels and internet-based video advertising lack the same reach; radio spots lack the visual impact; and newspaper and billboard ads lack sound and motion, as do many internet search engine and Web site banner ads. Through information provided during individualized price negotiations, stations can readily identify advertisers with strong preferences for using broadcast television spot advertising and ultimately can charge different advertisers different prices. Consequently, a small but significant price increase in broadcast television spot advertising is unlikely to cause enough advertising customers to switch advertising purchases to other media to make the price increase unprofitable.

2. The Relevant Markets

The Complaint alleges that each of the DMA Markets constitutes a relevant geographic market for purposes of analyzing this acquisition under Section 7 of the Clayton Act. A.C. Nielsen

Company defines DMAs as specific geographic units for advertising purposes. Signals from full-powered television stations in each of the DMA Markets reach viewers throughout that DMA, so advertisers can use television stations in each of the DMA Markets to target the largest possible number of viewers within each of those markets. Some of these advertisers are located in each of the DMA Markets and are trying to reach consumers that live in that specific market; others are regional or national businesses wanting to target consumers in a specific area. Advertising on television stations outside each of the DMA Markets is not an alternative for either local, regional, or national advertisers, because signals from television stations outside each of the DMA Markets reach relatively few viewers within each of those DMAs. Thus, advertising on those stations outside a DMA does not reach a significant number of potential customers within the DMA.

3. Harm to Competition in Each of the DMA Markets

The Complaint alleges that the proposed acquisition likely would lessen competition substantially in interstate trade and commerce, in violation of Section 7 of the Clayton Act, 15 U.S.C. 18, and likely would have the following effects, among others:

- (a) Competition in the sale of broadcast television spot advertising in each of the DMA Markets would be lessened substantially;
- (b) competition between Media General broadcast television stations and LIN broadcast television stations in the sale of broadcast television spot advertising in each of the DMA Markets would be eliminated; and
- (c) the prices for spot advertising time on broadcast television stations in each of the DMA Markets likely would increase.

Both Defendants own and operate network-affiliated broadcast television stations in each of the DMA Markets. The acquisition, by eliminating LIN as a separate competitor and combining its operations with Media General, would allow the combined entity to increase its market share of the broadcast television spot advertising and revenues in each of the DMA Markets. In the Mobile, Alabama/Pensacola, Florida DMA, combining the three stations that Defendants operate would give Media General approximately 54 percent of all television station gross advertising revenues in that DMA. In the Birmingham, Alabama DMA, combining the two stations that Defendants operate would give Media General

approximately 34 percent of all television station gross advertising revenues in that DMA. In the Savannah, Georgia DMA, combining the three stations that Defendants operate would give Media General approximately 55 percent of all television station gross advertising revenues in that DMA. In the Providence, Rhode Island/New Bedford, Massachusetts DMA, combining the three stations that Defendants operate would give Media General approximately 83 percent of all television station gross advertising revenues in that DMA. Finally, in the Green Bay/Appleton, Wisconsin DMA, combining the three stations that Defendants operate would give Media General approximately 59 percent of all television station gross advertising revenues in that DMA. In addition to increasing Media General's share of broadcast television spot advertising revenue in each of the DMA Markets, the proposed acquisition would increase substantially its concentration in each of the DMA Markets.

Using the Herfindahl-Hirschman Index ("HHI"), a standard measure of market concentration (defined and explained in Appendix A to the Complaint), the post-acquisition HHI in each of the DMA Markets would be over 2500 with an increase in the HHI of more than 500 points in each of those markets. Under the Horizontal Merger Guidelines issued by the Department of Justice and Federal Trade Commission, mergers resulting in highly concentrated markets (with an HHI in excess of 2500) with an increase in the HHI of more than 200 points are presumed to be likely to enhance market power.

The transaction also combines stations that are close substitutes and vigorous competitors in a product market with limited alternatives. In each of the DMA Markets, Defendants have broadcast stations that are affiliated with the major national television networks, ABC, CBS, NBC, and FOX. Their respective affiliations with those networks, and their local news operations, provide Defendants' stations with a variety of competing programming options that are often each other's next-best or second-best substitutes for viewers and advertisers.

Currently, Defendants' stations that overlap in the same DMA Market compete for the business of local, regional, and national firms seeking to advertise on broadcast television stations. Advertisers benefit from this competition. Thus, the proposed acquisition is likely to eliminate this head-to-head competition and therefore, could enable Defendants to raise prices for broadcast spot advertising.

4. Lack of Countervailing Factors

The Complaint alleges that entry or expansion in each of the DMA Markets' television spot advertising market would not be timely, likely, or sufficient to prevent any anticompetitive effects. New entry is unlikely since any new station would require an FCC license, which is difficult to obtain. Even if a new station became operational, commercial success would come over a period of many years. The number of 30-second spots available at a station is generally fixed, and additional slots cannot be created. Adjusting programming in response to a pricing change is difficult and time-consuming. Programming schedules are complex and carefully constructed, and television stations often have multi-year contractual commitments for individual shows or are otherwise committed to programming provided by their affiliated network. Accordingly, other television stations in each of the DMA Markets could not readily increase their advertising capacity or change their programming in response to a small but significant price increase by Media General.

III. Explanation of the Proposed Final Judgment

The divestiture requirement of the proposed Final Judgment will eliminate the anticompetitive effects of the transaction in each of the DMA Markets by maintaining the Divestiture Stations as independent, economically viable competitors.¹ The proposed Final Judgment requires Defendants to make the following divestitures: To Hearst Television: WVTM-TV, located in Birmingham, Alabama and WJCL, located in Savannah, Georgia; to Meredith Corporation: WALA-TV, located in Mobile, Alabama; and to

Sinclair Broadcast Group: WJAR, located in Providence, Rhode Island, WLUK-TV and WCWF, both located in Green Bay, Wisconsin, and WTGS, located in Savannah, Georgia.² The United States has approved each of these divestitures in order to provide greater certainty and efficiency in the divestiture process. Defendants must take all reasonable steps necessary to accomplish the divestiture quickly. If Defendants do not sell the assets to the approved buyers, they shall cooperate with prospective purchasers to accomplish the divestiture expeditiously to other Acquirers in such a way as to satisfy the United States in its sole discretion that the Divestiture Stations can and will be operated by a purchaser as a viable, ongoing business that can compete effectively in the relevant market.

The "Divestiture Assets" are defined in Paragraph II.O of the proposed Final Judgment to include all assets principally devoted to and necessary for the operation of the Divestiture Stations. These Divestiture Assets are essentially the same assets that Defendants would have operated under the Asset Purchase Agreement. The assets include real property, equipment, FCC licenses, contracts, intellectual property rights, programming materials, and customer lists maintained by Media General or LIN in connection with each of the Divestiture Stations. These do not include assets that are not principally devoted to or necessary for the operation of each of the Divestiture Stations, but are used to support multiple stations. Thus, Media General will be able to retain back-office systems or other assets and contracts used to support multiple broadcast television stations, and which an Acquirer with experience operating broadcast television stations can supply for itself.

To ensure that each of the Divestiture Stations is operated as an independent, economically viable competitor after the divestitures, Section XI of the proposed Final Judgment prohibit Defendants from entering into any agreements during the term of the Final Judgment that create a long-term relationship with any of the Acquirers of the Divestiture Stations after the divestitures are completed. Examples of prohibited agreements include options to repurchase or assign interests in any of the Divestiture Stations; agreements to

provide financing or guarantees for financing; local marketing agreements, joint sales agreements, or any other cooperative selling arrangements; shared services agreements; and agreements to jointly conduct any business negotiations with the Acquirers with respect to any of the Divestiture Stations. This shared services prohibition does not preclude agreements limited to helicopter sharing and stock video pooling in the forms that are customary in the industry. It also does not preclude other non-sales-related agreements approved in advance by the United States in its sole discretion. These limited exceptions do not permit Defendants to enter into broad news-sharing agreements with respect to any of the Divestiture Stations. The United States in its sole discretion may approve in writing of any transition services agreement that may be necessary to facilitate the continuous operations of the Divestiture Assets until the Acquirers can provide such capabilities independently. The terms and conditions of any such transition services agreement shall be subject to the approval of the United States, in its sole discretion. These transition services agreements will allow each of the Divestiture Stations to continue its operations as an independent, ongoing, economically viable, and active competitor in the broadcast television spot advertising business.

Defendants are required to take all steps reasonably necessary to accomplish the divestitures quickly and to cooperate with prospective purchasers. Because transferring the broadcast license for each of the Divestiture Stations requires FCC approval, Defendants are specifically required to use their best efforts to obtain all necessary FCC approvals as expeditiously as possible. The divestiture of each of the Divestiture Stations must occur within ninety (90) calendar days after the filing of the Hold Separate in this matter or five (5) calendar days after notice that the Court has entered the Final Judgment, whichever is later, subject to Defendants' receipt of any necessary FCC order pertaining to the divestiture. The United States, in its sole discretion, may agree to one or more extensions of this time period not to exceed sixty (60) calendar days in total, and shall notify the Court in such circumstances. If FCC applications to assign or transfer licenses to the Acquirers of the Divestiture Stations have been filed within the period permitted for divestiture, but an order or other

¹ The United States' evaluation of the merger of Media General and LIN concerned the likely competitive effects of the merger, and did not consider whether pre-existing agreements among participants in the DMA Markets might restrain competition. For instance, the United States is aware that, before Defendants entered their agreement to merge, LIN had a pre-existing local marketing agreement (LMA) in Providence with the owner of the Fox affiliate. Following the divestitures required under the proposed Final Judgment, Media General will replace LIN under the LMA. Because the United States has not investigated the competitive effects of these agreements as part of its evaluation of the merger, the proposed Final Judgment does not address them. We understand, however, that LMAs or other agreements in these markets may be subject to the requirements established in the Federal Communications Commission's Report and Order in its *2014 Quadrennial Regulatory Review—Review of the Commission's Broadcast Ownership Rules and Other Rules Adopted Pursuant to Section 202 of the Telecommunications Act of 1996*, MB Docket No. 14–50, FCC 14–28 (Apr. 15, 2014).

² Vaughan Acquisition LLC owns certain equity interests in WTGS, and Defendant LIN holds an option to purchase Vaughan's equity interests in WTGS. LIN and Vaughan have entered into an Option Exercise Agreement pursuant to which LIN will exercise its option for Sinclair's benefit upon consummation of Media General's merger with LIN.

dispositive action by FCC on such applications has not been issued before the end of the period permitted for divestiture, the period shall be extended with respect to divestiture of the Divestiture Stations for which no FCC order has issued until five (5) days after such order is issued.

If the divestitures do not occur within the prescribed timeframe in Section VI (A) of the proposed Final Judgment, the proposed Final Judgment provides that the Court, upon application of the United States, will appoint a Divestiture Trustee selected by the United States to sell any of the Divestiture Stations that have not been divested. The Defendants will pay all costs and expenses of the Divestiture Trustee. The Divestiture Trustee's commission will be structured to provide an incentive for the Divestiture Trustee based on the price obtained and the speed with which the divestiture is accomplished. The Divestiture Trustee would file monthly reports with the Court and the United States describing efforts to divest the remaining stations. If the divestiture has not been accomplished after six (6) months, the Divestiture Trustee and the United States will make recommendations to the Court, which shall enter such orders as appropriate, to carry out the purpose of the trust.

IV. Remedies Available to Potential Private Litigants

Section 4 of the Clayton Act, 15 U.S.C. 15, provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages the person has suffered, as well as costs and reasonable attorneys' fees. Entry of the proposed Final Judgment will neither impair nor assist the bringing of any private antitrust damage action. Under the provisions of Section 5(a) of the Clayton Act, 15 U.S.C. 16(a), the proposed Final Judgment has no prima facie effect in any subsequent private lawsuit that may be brought against Defendants.

V. Procedures Available for Modification of the Proposed Final Judgment

The United States and Defendants have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry upon the Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least sixty (60) days preceding the effective date of the proposed Final

Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within sixty (60) days of the date of publication of this Competitive Impact Statement in the **Federal Register**, or the last date of publication in a newspaper of the summary of this Competitive Impact Statement, whichever is later. All comments received during this period will be considered by the U.S. Department of Justice, which remains free to withdraw its consent to the proposed Final Judgment at any time prior to the Court's entry of judgment. The comments and the response of the United States will be filed with the Court. In addition, comments will be posted on the United States Department of Justice, Antitrust Division's internet Web site and, under certain circumstances, published in the **Federal Register**.

Written comments should be submitted to: David C. Kully, Chief, Litigation III Section, Antitrust Division, United States Department of Justice, 450 5th Street NW., Suite 4000, Washington, DC 20530. The proposed Final Judgment provides that the Court retains jurisdiction over this action, and Defendants may apply to the Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the Final Judgment.

VI. Alternatives to the Proposed Final Judgment

The United States considered, as an alternative to the proposed Final Judgment, a full trial on the merits against Defendants. The United States could have continued the litigation and sought preliminary and permanent injunctions against Media General's acquisition of LIN. The United States is satisfied, however, that the divestiture of assets described in the proposed Final Judgment will preserve competition for the sale of broadcast television spot advertising in each of the DMA Markets. Thus, the proposed Final Judgment would achieve all or substantially all of the relief the United States would have obtained through litigation, but avoids the time, expense, and uncertainty of a full trial on the merits of the Complaint.

VII. Standard of Review Under the APPA for the Proposed Final Judgment

The Clayton Act, as amended by the APPA, requires that proposed consent judgments in antitrust cases brought by the United States be subject to a sixty-day comment period, after which the court shall determine whether entry of

the proposed Final Judgment "is in the public interest." 15 U.S.C. 16(e)(1). In making that determination, the court, in accordance with the statute as amended in 2004, is required to consider:

(A) The competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and

(B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. 16(e)(1)(A) & (B). In considering these statutory factors, the court's inquiry is necessarily a limited one as the government is entitled to "broad discretion to settle with the defendant within the reaches of the public interest." *United States v. Microsoft Corp.*, 56 F.3d 1448, 1461 (D.C. Cir. 1995); *see generally United States v. SBC Commc'ns, Inc.*, 489 F. Supp. 2d 1 (D.D.C. 2007) (assessing public interest standard under the Tunney Act); *United States v. InBev N.V./S.A.*, 2009–2 Trade Cas. (CCH) ¶ 76,736, 2009 U.S. Dist. LEXIS 84787, No. 08–1965 (JR), at *3, *InBev N.V./S.A.*, 2009–2 Trade Cas. (CCH) ¶ 76,736, 2009 U.S. Dist. LEXIS 84787, No. 08–1965 (JR), at *3, (D.D.C. Aug. 11, 2009) (noting that the court's review of a consent judgment is limited and only inquires "into whether the government's determination that the proposed remedies will cure the antitrust violations alleged in the complaint was reasonable, and whether the mechanism to enforce the final judgment are clear and manageable.").³

As the United States Court of Appeals for the District of Columbia Circuit has held, under the APPA a court considers, among other things, the relationship between the remedy secured and the specific allegations set forth in the government's complaint, whether the decree is sufficiently clear, whether the enforcement mechanisms are sufficient,

³ The 2004 amendments substituted "shall" for "may" in directing relevant factors for court to consider and amended the list of factors to focus on competitive considerations and to address potentially ambiguous judgment terms. *Compare* 15 U.S.C. 16(e) (2004) *with* 15 U.S.C. 16(e)(1) (2006); *see also SBC Commc'ns*, 489 F. Supp. 2d at 11 (concluding that the 2004 amendments "effected minimal changes" to Tunney Act review).

and whether the decree may positively harm third parties. *See Microsoft*, 56 F.3d at 1458–62. With respect to the adequacy of the relief secured by the decree, a court may not “engage in an unrestricted evaluation of what relief would best serve the public.” *United States v. BNS, Inc.*, 858 F.2d 456, 462 (9th Cir. 1988) (quoting *United States v. Bechtel Corp.*, 648 F.2d 660, 666 (9th Cir. 1981)); *see also Microsoft*, 56 F.3d at 1460–62; *United States v. Alcoa, Inc.*, 152 F. Supp. 2d 37, 40 (D.D.C. 2001); *InBev*, 2009 U.S. Dist. LEXIS 84787, at *3. Courts have held that:

[t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General. The court’s role in protecting the public interest is one of insuring that the government has not breached its duty to the public in consenting to the decree. The court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is “within the reaches of the public interest.” More elaborate requirements might undermine the effectiveness of antitrust enforcement by consent decree.

Bechtel, 648 F.2d at 666 (emphasis added) (citations omitted).⁴ In determining whether a proposed settlement is in the public interest, a district court “must accord deference to the government’s predictions about the efficacy of its remedies, and may not require that the remedies perfectly match the alleged violations.” *SBC Commc’ns*, 489 F. Supp. 2d at 17; *see also U.S. Airways*, 2014 U.S. Dist. LEXIS 57801, at *16 (noting that a court should not reject the proposed remedies because it believes others are preferable); *Microsoft*, 56 F.3d at 1461 (noting the need for courts to be “deferential to the government’s predictions as to the effect of the proposed remedies”); *United States v. Archer-Daniels-Midland Co.*, 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (noting that the court should grant due respect to the United States’ prediction as to the effect of proposed remedies, its perception of the market structure, and its views of the nature of the case).

Courts have greater flexibility in approving proposed consent decrees

than in crafting their own decrees following a finding of liability in a litigated matter. “[A] proposed decree must be approved even if it falls short of the remedy the court would impose on its own, as long as it falls within the range of acceptability or is ‘within the reaches of public interest.’” *United States v. Am. Tel. & Tel. Co.*, 552 F. Supp. 131, 151 (D.D.C. 1982) (citations omitted) (quoting *United States v. Gillette Co.*, 406 F. Supp. 713, 716 (D. Mass. 1975)), *aff’d sub nom. Maryland v. United States*, 460 U.S. 1001 (1983); *see also U.S. Airways*, 2014 U.S. Dist. LEXIS 57801, at *8 (noting that room must be made for the government to grant concessions in the negotiation process for settlements (citing *Microsoft*, 56 F.3d at 1461); *United States v. Alcan Aluminum Ltd.*, 605 F. Supp. 619, 622 (W.D. Ky. 1985) (approving the consent decree even though the court would have imposed a greater remedy). To meet this standard, the United States “need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.” *SBC Commc’ns*, 489 F. Supp. 2d at 17.

Moreover, the court’s role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its Complaint, and does not authorize the court to “construct [its] own hypothetical case and then evaluate the decree against that case.” *Microsoft*, 56 F.3d at 1459; *see also U.S. Airways*, 2014 U.S. Dist. LEXIS 57801, at *9 (noting that the court must simply determine whether there is a factual foundation for the government’s decisions such that its conclusions regarding the proposed settlements are reasonable; *InBev*, 2009 U.S. Dist. LEXIS 84787, at *20 (“the ‘public interest’ is not to be measured by comparing the violations alleged in the complaint against those the court believes could have, or even should have, been alleged”). Because the “court’s authority to review the decree depends entirely on the government’s exercising its prosecutorial discretion by bringing a case in the first place,” it follows that “the court is only authorized to review the decree itself,” and not to “effectively redraft the complaint” to inquire into other matters that the United States did not pursue. *Microsoft*, 56 F.3d at 1459–60. As this Court recently confirmed in *SBC Communications*, courts “cannot look beyond the complaint in making the public interest determination unless the complaint is drafted so narrowly as to make a mockery of judicial power.” *SBC Commc’ns*, 489 F. Supp. 2d at 15.

In its 2004 amendments, Congress made clear its intent to preserve the practical benefits of utilizing consent decrees in antitrust enforcement, adding the unambiguous instruction that “[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.” 15 U.S.C. 16(e)(2); *see also U.S. Airways*, 2014 U.S. Dist. LEXIS 57801, at *9 (indicating that a court is not required to hold an evidentiary hearing or to permit intervenors as part of its review under the Tunney Act). The language wrote into the statute what Congress intended when it enacted the Tunney Act in 1974, as Senator Tunney explained: “[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.” 119 Cong. Rec. 24,598 (1973) (statement of Sen. Tunney). Rather, the procedure for the public interest determination is left to the discretion of the court, with the recognition that the court’s “scope of review remains sharply proscribed by precedent and the nature of Tunney Act proceedings.” *SBC Commc’ns*, 489 F. Supp. 2d at 11.⁵ A court can make its public interest determination based on the competitive impact statement and response to public comments alone. *U.S. Airways*, 2014 U.S. Dist. LEXIS 57801, at *9.

VIII. Determinative Documents

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.
Dated: October 30, 2014
Respectfully submitted,
/s/

Mark A. Merva * (D.C. Bar #451743)
Anupama Sawkar, *Trial Attorneys*,
United States Department of Justice,
Antitrust Division, Litigation III Section,

⁵ *See United States v. Enova Corp.*, 107 F. Supp. 2d 10, 17 (D.D.C. 2000) (noting that the “Tunney Act expressly allows the court to make its public interest determination on the basis of the competitive impact statement and response to comments alone”); *United States v. Mid-Am. Dairymen, Inc.*, 1977–1 Trade Cas. (CCH) ¶ 61,508, at 71,980 (W.D. Mo. 1977) (“Absent a showing of corrupt failure of the government to discharge its duty, the Court, in making its public interest finding, should . . . carefully consider the explanations of the government in the competitive impact statement and its responses to comments in order to determine whether those explanations are reasonable under the circumstances.”); S. Rep. No. 93–298, 93d Cong., 1st Sess., at 6 (1973) (“Where the public interest can be meaningfully evaluated simply on the basis of briefs and oral arguments, that is the approach that should be utilized.”).

⁴ *Cf. BNS*, 858 F.2d at 464 (holding that the court’s “ultimate authority under the [APPA] is limited to approving or disapproving the consent decree”); *United States v. Gillette Co.*, 406 F. Supp. 713, 716 (D. Mass. 1975) (noting that, in this way, the court is constrained to “look at the overall picture not hypercritically, nor with a microscope, but with an artist’s reducing glass”). *See generally Microsoft*, 56 F.3d at 1461 (discussing whether “the remedies [obtained in the decree are] so inconsonant with the allegations charged as to fall outside of the ‘reaches of the public interest’”).

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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

United States of America, Plaintiff, v.
Media General, Inc., and *LIN Media
LLC*, Defendants.

Case No. 1:14-cv-01823

Judge: Hon. Emmet G. Sullivan

Filed: 10/30/2014

Certificate of Service

I, Mark A. Merva, hereby certify that on October 30, 2014, I caused copies of the Complaint, Competitive Impact Statement, Hold Separate Stipulation and Order, Proposed Final Judgment, and Plaintiff's Explanation of Consent Decree Procedures to be served upon Defendants Media General, Inc. and LIN Media LLC. by mailing the documents electronically to the duly authorized legal representatives of Defendants as follows: Counsel for Defendant Media General, Inc.: Richard C. Park (D.C. Bar #458426), Fried, Frank, Harris, Shriver & Jacobson LLP, 801 17th Street NW., Washington, DC 20006, Telephone: 202-639-7064, Facsimile: 202-639-7003, Email: richard.park@friedfrank.com.

Counsel for LIN Media LLC: Deborah A. Garza (D.C. Bar #359259), Covington & Burling LLP, 1201 Pennsylvania Avenue NW., Washington, DC 20004, Telephone: 202-662-5146, Facsimile: 202-778-5146, Email: dgarza@cov.com. Respectfully submitted,
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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

United States of America, Plaintiff, v.
Media General, Inc., and *LIN Media
LLC*, Defendants.

Case No. 1:14-cv-01823

Judge: Hon. Emmet G. Sullivan

Filed: 10/30/2014

Proposed Final Judgment

WHEREAS, plaintiff, the United States of America filed its Complaint on October 30, 2014, and Defendant Media General, Inc. ("Media General") and Defendant LIN Media LLC ("LIN"), by

their respective attorneys, have consented to the entry of this Final Judgment without trial or adjudication of any issue of fact or law, and without this Final Judgment constituting any evidence against or admission by any party regarding any issue of fact;

AND WHEREAS, Defendants agree to be bound by the provisions of this Final Judgment pending its approval by the Court;

AND WHEREAS, the essence of this Final Judgment is the prompt and certain divestiture of certain rights or assets by the Defendants to assure that competition is not substantially lessened;

AND WHEREAS, the United States requires Defendants to make certain divestitures for the purpose of remedying the loss of competition alleged in the Complaint;

AND WHEREAS, Defendants have represented to the United States that the divestitures required below can and will be made and that Defendants will later raise no claim of hardship or difficulty as grounds for asking the Court to modify any of the divestiture provisions contained below;

NOW THEREFORE, before any testimony is taken, without trial or adjudication of any issue of fact or law, and upon consent of the parties, it is ORDERED, ADJUDGED, AND DECREED:

I. Jurisdiction

This Court has jurisdiction over each of the parties hereto and over the subject matter of this action. The Complaint states a claim upon which relief may be granted against Defendants under Section 7 of the Clayton Act, as amended, 15 U.S.C. 18.

II. Definitions

As used in this Final Judgment:

A. "Media General" means Defendant Media General, Inc., a Virginia corporation headquartered in Richmond, Virginia, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

B. "LIN" means Defendant LIN Media LLC, a Delaware corporation headquartered in Austin, Texas, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

C. "Acquirer" means Hearst Television Inc., Meredith Corporation, Sinclair Broadcast Group, Inc., or another entity to whom Defendants divest any of the Divestiture Assets.

D. "Hearst" means Hearst Television Inc., a Delaware corporation headquartered in New York, NY, its successor and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

E. "Meredith" means Meredith Corporation, an Iowa corporation headquartered in Des Moines, IA, its successor and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

F. "Sinclair" means Sinclair Broadcast Group, Inc., a Maryland corporation headquartered in Hunt Valley, Maryland, its successor and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

G. "DMA" means Designated Market Area as defined by A.C. Nielsen Company based upon viewing patterns and used by the *Investing in Television BIA Market Report 2014* (1st edition). DMAs are ranked according to the number of households therein and are used by broadcasters, advertisers, and advertising agencies to aid in evaluating television audience size and composition.

H. "WVTM-TV" means the NBC-affiliated broadcast television station located in the Birmingham, Alabama DMA owned by Defendant Media General.

I. "WJCL" means the ABC-affiliated broadcast television station located in the Savannah, Georgia DMA owned by Defendant LIN.

J. "WALA-TV" means the Fox-affiliated broadcast television station located in the Mobile, Alabama/Pensacola, Florida DMA owned by Defendant LIN.

K. "WJAR" means the NBC-affiliated broadcast television station located in the Providence, Rhode Island/New Bedford, Massachusetts DMA owned by Defendant Media General.

L. "WLUK-TV" means the Fox-affiliated broadcast television station located in the Green Bay/Appleton, Wisconsin DMA owned by Defendant LIN.

M. "WCWF" means the CW-affiliated broadcast television station located in the Green Bay/Appleton, Wisconsin DMA owned by Defendant LIN.

N. "WTGS" means the Fox-affiliated broadcast television station located in the Savannah, Georgia DMA.

O. "Divestiture Assets" means all assets, tangible or intangible, principally devoted to and necessary for the

operations of WVTM-TV, WJCL, WALA-TV, WJAR, WLUK-TV, WCWF, and WTGS as viable, ongoing commercial broadcast television stations, including, but not limited to, all real property (owned or leased) principally devoted to and necessary for the operation of the stations, all broadcast equipment, office equipment, office furniture, fixtures, materials, supplies, and other tangible property principally devoted to and necessary for the operation of the stations; all licenses, permits, authorizations, and applications therefore issued by the Federal Communications Commission ("FCC") and other government agencies related to the stations; all contracts (including programming contracts and rights), agreements, network affiliation agreements, leases, and commitments and understandings of Defendants principally devoted to and necessary for the operation of the stations; all trademarks, service marks, trade names, copyrights, patents, slogans, programming materials, and promotional materials relating to the stations; all customer lists, contracts, accounts, and credit records; and all logs and other records maintained by Defendants in connection with the stations.

III. Applicability

A. This Final Judgment applies to Defendants, and all other persons in active concert or participation with any of them who receive actual notice of this Final Judgment by personal service or otherwise.

B. If, prior to complying with Sections IV and V of this Final Judgment, Defendants sell or otherwise dispose of all or substantially all of their assets or of lesser business units that include the Defendants' Divestiture Assets, they shall require the purchaser to be bound by the provisions of this Final Judgment. Defendants need not obtain such an agreement from the Acquirers of the assets divested pursuant to this Final Judgment.

IV. Divestitures

A. Defendants are ordered and directed, within ninety (90) calendar days after the filing of the Hold Separate Stipulation and Order in this matter or five (5) calendar days after notice of the entry of this Final Judgment by the Court, whichever is later, to divest the Divestiture Assets to one or more Acquirers acceptable to the United States, in its sole discretion. The United States, in its sole discretion, may agree to one or more extensions of this time period not to exceed sixty (60) calendar days in total, and shall notify the Court

in such circumstances. With respect to divestiture of the Divestiture Assets by Defendants or a Divestiture Trustee appointed pursuant to Section V of this Final Judgment, if applications have been filed with the FCC within the period permitted for divestiture seeking approval to assign or transfer licenses to the Acquirers of the Divestiture Assets, but an order or other dispositive action by the FCC on such applications has not been issued before the end of the period permitted for divestiture, the period shall be extended with respect to divestiture of the Divestiture Assets for which no FCC order has issued until five (5) days after such order is issued. Defendants agree to use their best efforts to divest the Divestiture Assets as expeditiously as possible, including using their best efforts to obtain all necessary FCC approvals as expeditiously as possible. This Final Judgment does not limit the FCC's exercise of its regulatory powers and process with respect to the Divestiture Assets. Authorization by the FCC to conduct the divestiture of a Divestiture Asset in a particular manner will not modify any of the requirements of this Final Judgment.

B. The United States in its sole discretion may approve in writing of any transition services agreement that may be necessary to facilitate the continuous operations of the Divestiture Assets until the Acquirers can provide such capabilities independently. The terms and conditions of any such transition services agreement shall be subject to the approval of the United States, in its sole discretion.

C. In the event that Defendants are attempting to divest assets related to WVTM-TV and WJCL to an Acquirer other than Hearst, assets related to WALA-TV to an Acquirer other than Meredith, or assets related to WJAR, WLUK-TV, WCWF, and WTGS to an Acquirer other than Sinclair:

(1) Defendants, in accomplishing the divestitures ordered by this Final Judgment, promptly shall make known, by usual and customary means, the availability of the Divestiture Assets not yet divested;

(2) Defendants shall inform any person making inquiry regarding a possible purchase of the applicable Divestiture Assets that they are being divested pursuant to this Final Judgment and provide that person with a copy of this Final Judgment;

(3) Defendants shall offer to furnish to all prospective Acquirers, subject to customary confidentiality assurances, all information and documents relating to the applicable Divestiture Assets customarily provided in a due diligence

process except such information or documents subject to the attorney-client privilege or work-product doctrine; and

(4) Defendants shall make available such information to the United States at the same time that such information is made available to any other person.

D. Defendants shall provide the Acquirers and the United States information relating to the personnel involved in the operation and management of the applicable Divestiture Assets to enable the Acquirers to make offers of employment. Defendants shall not interfere with any negotiations by the Acquirers to employ or contract with any employee of any Defendant whose primary responsibility relates to the operation or management of the applicable Divestiture Assets being sold by the Acquirers.

E. Defendants shall permit the Acquirers of the Divestiture Assets to have reasonable access to personnel and to make inspections of the physical facilities of the applicable stations; access to any and all environmental, zoning, and other permit documents and information; and access to any and all financial, operational, or other documents and information customarily provided as part of a due diligence process.

F. Defendants shall warrant to the Acquirers that each Divestiture Asset will be operational on the date of sale.

G. Defendants shall not take any action that will impede in any way the permitting, operation, or divestiture of the Divestiture Assets.

H. Defendants shall warrant to the Acquirers that there are no material defects in the environmental, zoning, or other permits pertaining to the operation of each asset, and that, following the sale of the Divestiture Assets, Defendants will not undertake, directly or indirectly, any challenges to the environmental, zoning, or other permits relating to the operation of the Divestiture Assets.

I. Unless the United States otherwise consents in writing, the divestitures pursuant to Section IV, or by trustee appointed pursuant to Section V of this Final Judgment, shall include the entire Divestiture Assets and be accomplished in such a way as to satisfy the United States, in its sole discretion, that the Divestiture Assets can and will be used by the Acquirers as part of a viable, ongoing commercial television broadcasting business. Divestiture of the Divestiture Assets may be made to one or more Acquirers, provided that in each instance it is demonstrated to the sole satisfaction of the United States that the Divestiture Assets will remain

viable, and the divestiture of such assets will achieve the purposes of this Final Judgment and remedy the competitive harm alleged in the Complaint. The divestitures, whether pursuant to Section IV or Section V of this Final Judgment:

(1) Shall be made to Acquirers that, in the United States' sole judgment, have the intent and capability (including the necessary managerial, operational, technical, and financial capability) of competing effectively in the commercial television broadcasting business; and

(2) shall be accomplished so as to satisfy the United States, in its sole discretion, that none of the terms of any agreement between Acquirers and Defendants gives Defendants the ability unreasonably to raise any of the Acquirers' costs, to lower any of the Acquirers' efficiency, or otherwise to interfere in the ability of any of the Acquirers to compete effectively.

V. Appointment of Trustee

A. If Defendants have not divested the Divestiture Assets within the time period specified in Section IV(A), Defendants shall notify the United States of that fact in writing, specifically identifying the Divestiture Assets that have not been divested. Upon application of the United States, the Court shall appoint a Divestiture Trustee selected by the United States and approved by the Court to effect the divestiture of the Divestiture Assets that have not yet been divested.

B. After the appointment of a Divestiture Trustee becomes effective, only the Divestiture Trustee shall have the right to sell the applicable Divestiture Assets. The Divestiture Trustee shall have the power and authority to accomplish the divestiture to an Acquirer acceptable to the United States at such price and on such terms as are then obtainable upon reasonable effort by the trustee, subject to the provisions of Sections IV, V, and VI of this Final Judgment, and shall have such other powers as this Court deems appropriate. Subject to Section V(D) of this Final Judgment, the Divestiture Trustee may hire at the cost and expense of Defendants any investment bankers, attorneys, or other agents, who shall be solely accountable to the trustee, reasonably necessary in the trustee's judgment to assist in the divestiture. Any such investment bankers, attorneys, or other agents shall serve on such terms and conditions as the United States approves, including confidentiality requirements and conflict of interest certifications.

C. Defendants shall not object to a sale by the trustee on any ground other than

the trustee's malfeasance. Any such objections by Defendants must be conveyed in writing to the United States and the Divestiture Trustee within ten (10) calendar days after the trustee has provided the notice required under Section VI.

D. The Divestiture Trustee shall serve at the cost and expense of Defendants pursuant to a written agreement, on such terms and conditions as the United States approves, including confidentiality requirements and conflict of interest certifications. The trustee shall account for all monies derived from the sale of the applicable Divestiture Assets and all costs and expenses so incurred. After approval by the Court of the trustee's accounting, including fees for its services yet unpaid and those of any professionals and agents retained by the trustee, all remaining money shall be paid to Defendants and the trust shall then be terminated. The compensation of the Divestiture Trustee and any professionals and agents retained by the trustee shall be reasonable in light of the value of the Divestiture Assets subject to sale by the Divestiture Trustee and based on a fee arrangement providing the trustee with an incentive based on the price and terms of the divestiture and the speed with which it is accomplished, but timeliness is paramount. If the Divestiture Trustee and Defendants are unable to reach agreement on the trustee's or any agents' or consultants' compensation or other terms and conditions of engagement within 14 calendar days of appointment of the trustee, the United States may, in its sole discretion, take appropriate action, including making a recommendation to the Court. The Divestiture Trustee shall, within three (3) business days of hiring any other professionals or agents, provide written notice of such hiring and the rate of compensation to Defendants and the United States.

E. Defendants shall use their best efforts to assist the Divestiture Trustee in accomplishing the required divestiture. The Divestiture Trustee and any consultants, accountants, attorneys, and other agents retained by the trustee shall have full and complete access to the personnel, books, records, and facilities of the business to be divested, and Defendants shall develop financial and other information relevant to such business as the trustee may reasonably request, subject to reasonable protection for trade secret or other confidential research, development, or commercial information or any applicable privileges. Defendants shall take no action to interfere with or to impede the

Divestiture Trustee's accomplishment of the divestiture.

F. After its appointment, the Divestiture Trustee shall file monthly reports with the United States and, as appropriate, the Court setting forth the trustee's efforts to accomplish the applicable divestiture ordered under this Final Judgment. To the extent such reports contain information that the Divestiture Trustee deems confidential, such report shall not be filed in the public docket of the Court. Such report shall include the name, address, and telephone number of each person who, during the preceding month, made an offer to acquire, expressed an interest in acquiring, entered into negotiations to acquire, or was contacted or made an inquiry about acquiring, any interest in the Divestiture Assets, and shall describe in detail each contact with any such person. The Divestiture Trustee shall maintain full records of all efforts made to divest the applicable Divestiture Assets.

G. If the Divestiture Trustee has not accomplished any applicable divestiture ordered under this Final Judgment within six (6) months after its appointment, the trustee shall promptly file with the Court a report setting forth (1) the trustee's efforts to accomplish the required divestiture, (2) the reasons, in the trustee's judgment, why the required divestiture has not been accomplished, and (3) the trustee's recommendations. To the extent such report contains information that the Divestiture Trustee deems confidential, such report shall not be filed in the public docket of the Court. The Divestiture Trustee shall at the same time furnish such report to the United States which shall have the right to make additional recommendations consistent with the purpose of the trust. The Court thereafter shall enter such orders as it shall deem appropriate to carry out the purpose of the Final Judgment, which may, if necessary, include extending the trust and the term of the Divestiture Trustee's appointment by a period requested by the United States.

H. If the United States determines that the Divestiture Trustee has ceased to act or failed to act diligently or in a reasonably cost-effective manner, it may recommend the Court appoint a substitute Divestiture Trustee.

VI. Notice of Proposed Divestiture

A. Within two (2) business days following execution of a definitive divestiture agreement, Defendants or the Divestiture Trustee, whichever is then responsible for effecting the divestitures required herein, shall notify the United States of any proposed divestiture

required by Section IV or V of this Final Judgment. If the Divestiture Trustee is responsible, it shall similarly notify Defendants. The notice shall set forth the details of the proposed divestiture and list the name, address, and telephone number of each person not previously identified who offered or expressed an interest in or desire to acquire any ownership interest in the Divestiture Assets, together with full details of the same.

B. Within fifteen (15) calendar days of receipt by the United States of such notice, the United States may request from Defendants, the proposed Acquirer, any other third party, or the Divestiture Trustee, if applicable, additional information concerning the proposed divestiture, the proposed Acquirer, and any other potential Acquirers. Defendants and the Divestiture Trustee shall furnish any additional information requested within fifteen (15) calendar days of the receipt of the request, unless the parties shall otherwise agree.

C. Within thirty (30) calendar days after receipt of the notice or within twenty (20) calendar days after the United States has been provided the additional information requested from Defendants, the proposed Acquirer, any third party, and the Divestiture Trustee, whichever is later, the United States shall provide written notice to Defendants and the Divestiture Trustee, if there is one, stating whether or not it objects to the proposed divestiture. If the United States provides written notice that it does not object, the divestiture may be consummated, subject only to Defendants' limited right to object to the sale under Section V(C) of this Final Judgment. Absent written notice that the United States does not object to the proposed Acquirer or upon objection by the United States, a divestiture proposed under Section IV or Section V shall not be consummated. Upon objection by Defendants under Section V(C), a divestiture proposed under Section V shall not be consummated unless approved by the Court.

VII. Financing

Defendants shall not finance all or any part of any purchase made pursuant to Section IV or V of this Final Judgment.

VIII. Hold Separate

Until the divestitures required by this Final Judgment has been accomplished, Defendants shall take all steps necessary to comply with the Hold Separate Stipulation and Order entered by this Court. Defendants shall take no action

that would jeopardize the divestiture ordered by this Court.

IX. Affidavits

A. Within twenty (20) calendar days of the filing of the Complaint in this matter, and every thirty (30) calendar days thereafter until the divestiture has been completed under Section IV or V of this Final Judgment, Defendants shall deliver to the United States an affidavit as to the fact and manner of their compliance with Section IV or V of this Final Judgment. Each such affidavit shall include the name, address, and telephone number of each person who, during the preceding thirty (30) calendar days, made an offer to acquire, expressed an interest in acquiring, entered into negotiations to acquire, or was contacted or made an inquiry about acquiring, any interest in the Divestiture Assets, and shall describe in detail each contact with any such person during that period. Each such affidavit shall also include a description of the efforts Defendants have taken to solicit buyers for and complete the sale of the Divestiture Assets, including efforts to secure FCC or other regulatory approvals, and to provide required information to prospective Acquirers, including the limitations, if any, on such information. Assuming the information set forth in the affidavit is true and complete, any objection by the United States to information provided by Defendants, including limitations on information, shall be made within fourteen (14) calendar days of receipt of such affidavit.

B. Within twenty (20) calendar days of the filing of the Complaint in this matter, Defendants shall deliver to the United States an affidavit that describes in reasonable detail all actions Defendants have taken and all steps Defendants have implemented on an ongoing basis to comply with Section VIII of this Final Judgment. Each such affidavit shall also include a description of the efforts Defendants have taken to complete the sale of the Divestiture Assets, including efforts to secure FCC or other regulatory approvals. Defendants shall deliver to the United States an affidavit describing any changes to the efforts and actions outlined in Defendants' earlier affidavits filed pursuant to this section within fifteen (15) calendar days after the change is implemented.

C. Defendants shall keep all records of all efforts made to preserve and divest the Divestiture Assets until one year after such divestiture has been completed.

X. Compliance Inspection

A. For the purposes of determining or securing compliance with this Final Judgment, or of any related orders such as any Hold Separate Stipulation and Order, or of determining whether the Final Judgment should be modified or vacated, and subject to any legally recognized privilege, from time to time authorized representatives of the United States Department of Justice, including consultants and other persons retained by the United States, shall, upon written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division, and on reasonable notice to Defendants, be permitted:

(1) Access during Defendants' office hours to inspect and copy, or at the option of the United States, to require Defendants to provide hard copies or electronic copy of, all books, ledgers, accounts, records, data, and documents in the possession, custody, or control of Defendants, relating to any matters contained in this Final Judgment; and

(2) to interview, either informally or on the record, Defendants' officers, employees, or agents, who may have their individual counsel present, regarding such matters. The interviews shall be subject to the reasonable convenience of the interviewee and without restraint or interference by Defendants.

B. Upon the written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division, Defendants shall submit written reports or responses to written interrogatories, under oath if requested, relating to any of the matters contained in this Final Judgment as may be requested.

C. No information or documents obtained by the means provided in this section shall be divulged by the United States to any person other than an authorized representative of the executive branch of the United States, except in the course of legal proceedings to which the United States is a party (including grand jury proceedings), or for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

D. If at the time information or documents are furnished by Defendants to the United States, Defendants represent and identify in writing the material in any such information or documents to which a claim of protection may be asserted under Rule 26(c)(1)(g) of the Federal Rules of Civil Procedure, and Defendants mark each pertinent page of such material, "Subject to claim of protection under

Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure,” then the United States shall give Defendants ten (10) calendar days notice prior to divulging such material in any legal proceeding (other than a grand jury proceeding).

XI. No Reacquisition or Other Prohibited Activities

Defendants may not (1) reacquire any part of the Divestiture Assets, (2) acquire any option to reacquire any part of the Divestiture Assets or to assign the Divestiture Assets to any other person, (3) enter into any local marketing agreement, joint sales agreement, other cooperative selling arrangement, or shared services agreement, or conduct other business negotiations jointly with the Acquirers with respect to the Divestiture Assets, or (4) provide financing or guarantees of financing with respect to the Divestiture Assets, during the term of this Final Judgment. The shared services prohibition does not preclude Defendants from continuing or entering into agreements in a form customarily used in the industry to (1) share news helicopters or (2) pool generic video footage that does not include recording a reporter or other on-air talent, and does not preclude Defendants from entering into any non-sales-related shared services agreement or transition services agreement that is approved in advance by the United States in its sole discretion.

XII. Retention of Jurisdiction

This Court retains jurisdiction to enable any party to this Final Judgment to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions.

XIII. Expiration of Final Judgment

Unless this Court grants an extension, this Final Judgment shall expire ten years from the date of its entry.

XIV. Public Interest Determination

Entry of this Final Judgment is in the public interest. The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16, including making copies available to the public of this Final Judgment, the Competitive Impact Statement, and any comments thereon, and the United States' responses to comments. Based upon the record before the Court, which includes the Competitive Impact Statement and any comments and response to comments

filed with the Court, entry of this Final Judgment is in the public interest.

Date:

Court approval subject to procedures of Antitrust Procedures and Penalties Act, 15 U.S.C. § 16

United States District Judge

[FR Doc. 2014-26886 Filed 11-12-14; 8:45 am]

BILLING CODE P

DEPARTMENT OF LABOR

Efforts by Certain Foreign Countries To Eliminate the Worst Forms of Child Labor

AGENCY: The Bureau of International Labor Affairs, United States Department of Labor.

ACTION: Notice: Request for information and invitation to comment.

SUMMARY: This notice is a request for information and/or comment on the 2013 Findings on the Worst Forms of Child Labor report (TDA report) issued by the Bureau of International Labor Affairs (ILAB) on October 7, 2014, regarding child labor in certain foreign countries. The recently published TDA report assessed efforts by more than 140 countries to reduce the worst forms of child labor and reported whether countries made significant, moderate, minimal, or no advancement. It also suggested actions foreign countries can take to eliminate the worst forms of child labor through legislation, enforcement, coordination, policies and social programs. This year's report introduced a new streamlined format for country profiles to make it more user-friendly and a better policy tool for engagement. Relevant information will be used by the Department of Labor (DOL) in preparation of its ongoing reporting mandated under the Trade and Development Act of 2000. In addition, ILAB will use relevant information to conduct assessments of each country's advancement toward eliminating the worst forms of child labor during the current calendar year compared to previous years.

DATES: Submitters of information are requested to provide their submission to the Office of Child Labor, Forced Labor, and Human Trafficking (OCFT) at the email or physical address below by 5 p.m. January 15, 2015.

To Submit Information: Information submitted to DOL should be submitted directly to OCFT, Bureau of International Labor Affairs, U.S. Department of Labor, at (202) 693-4843 (this is not a toll free number).

Comments, identified as “Docket No. DOL-2014-0009”, may be submitted by any of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>.

The portal includes instructions for submitting comments. Parties submitting responses electronically are encouraged not to submit paper copies.

Facsimile (fax): OCFT at 202-693-4830.

Mail, Express Delivery, Hand Delivery, and Messenger Service (1 copy): Chanda Uluca and Charita Castro at U.S.

Department of Labor, OCFT, Bureau of International Labor Affairs, 200 Constitution Avenue NW., Room S-5317, Washington, DC 20210.

Email: Email submissions should be addressed to both Chanda Uluca (Uluca.Chanda@dol.gov) and Charita Castro (Castro.Charita.L@dol.gov).

FOR FURTHER INFORMATION CONTACT: Chanda Uluca and Charita Castro (see contact information above).

SUPPLEMENTARY INFORMATION:

The Trade and Development Act of 2000 (TDA), Public Law 106-200 (2000), established a new eligibility criterion for receipt of trade benefits under the Generalized System of Preferences (GSP), Caribbean Basin Trade and Partnership Act (CBTPA), and Africa Growth and Opportunity Act (AGOA) and the Andean Trade Preference Act/Andean Trade Promotion and Drug Eradication Act (ATPA/ATPDEA).

The TDA amended the GSP reporting requirements of Section 504 of the Trade Act of 1974, 19 U.S.C. 2464, to require that the President's annual report on the status of internationally recognized worker rights include “findings by the Secretary of Labor with respect to the beneficiary country's implementation of its international commitments to eliminate the worst forms of child labor.” Title II of the TDA and the TDA Conference Report, Joint Explanatory Statement of the Committee of Conference, 106th Cong. 2d Sess. (2000), indicate that the same criterion applies for the receipt of benefits under CBTPA and AGOA, respectively. In addition, the Andean Trade Preference Act, as amended and expanded by the Andean Trade Promotion and Drug Eradication Act, Public Law 107-210, Title XXXI (2002), includes as a criterion for receiving benefits “[w]hether the country has implemented its commitments to eliminate the worst forms of child labor as defined in section 507(6) of the Trade Act of 1974.”

DOL fulfills these reporting mandates through annual publication of the U.S. Department of Labor's Findings on the

Worst Forms of Child Labor with respect to countries eligible for the aforementioned programs. The 2013 report and additional background information are available on the Internet at <http://www.dol.gov/ilab/reports/child-labor/findings/>.

Information Requested and Invitation to Comment: Interested parties are invited to comment and provide information regarding DOL's 2013 TDA Report which may be found on the Internet at <http://www.dol.gov/ilab/reports/child-labor/findings/> or obtained from OCFT. DOL requests comments or information to update the findings and suggestions for government action for countries reviewed in the TDA Report, as well as to assess each country's individual advancement toward eliminating the worst forms of child labor during the current reporting period compared to previous years. For more information on the types of issues covered in the TDA Report, please see Appendix II of the report. Materials submitted should be confined to the specific topics of the TDA report. DOL will generally consider sources with dates up to five years old (i.e., data not older than January 1, 2010). DOL appreciates the extent to which submissions clearly indicate the time period to which they apply. In the interest of transparency, classified information will not be accepted. Where applicable, information submitted should indicate its source or sources, and copies of the source material should be provided. If primary sources are utilized, such as research studies, interviews, direct observations, or other sources of quantitative or qualitative data, details on the research or data-gathering methodology should be provided. Please see the 2013 TDA Report for a complete explanation of relevant terms, definitions, and reporting guidelines employed by DOL.

This notice is a general solicitation of comments from the public.

Signed at Washington, DC, this 6th day of November 2014.

Carol Pier,

Deputy Undersecretary for International Affairs.

[FR Doc. 2014-26845 Filed 11-12-14; 8:45 am]

BILLING CODE 4510-28-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA-2011-0194]

Cotton Dust Standard; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning its proposal to extend the Office of Management and Budget's (OMB) approval of the information collection requirements specified in the Cotton Dust Standard (29 CFR 1910.1043).

DATES: Comments must be submitted (postmarked, sent, or received) by January 12, 2015.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at <http://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages you may fax them to the OSHA Docket Office at (202) 693-1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, OSHA Docket No. OSHA-2011-0194, Occupational Safety and Health Administration, U.S. Department of Labor, Room N-2625, 200 Constitution Avenue NW., Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m. to 4:45 p.m., e.t.

Instructions: All submissions must include the Agency name and the OSHA docket number (OSHA-2011-0194) for the Information Collection Request (ICR). All comments, including any personal information you provide, are placed in the public docket without change, and may be made available online at <http://www.regulations.gov>. For further information on submitting comments see the "Public Participation" heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

Docket: To read or download comments or other material in the docket, go to <http://www.regulations.gov> or the OSHA Docket Office at the address above. All documents in the docket (including this **Federal Register** notice) are listed in the <http://www.regulations.gov> index; however, some information (e.g., copyrighted material) is not publicly available to read or download from the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You may also contact Theda Kenney at the address below to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT:

Theda Kenney or Todd Owen, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, Room N-3468, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693-2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (i.e., employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accord with the Paperwork Reduction Act of 1995 (PRA-95) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the OSH Act) (29 U.S.C. 651 et seq.) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of efforts in obtaining information (29 U.S.C. 657).

The information collection requirements specified in the Cotton Dust Standard protect workers from the adverse health effects that may result from their exposure to cotton dust. The major information collection requirements of the Cotton Dust Standard include: performing exposure monitoring, including initial, periodic,

and additional monitoring; notifying each worker of their exposure monitoring results either in writing or by posting; implementing a written compliance program; and establishing a respiratory protection program in accord with OSHA's Respiratory Protection Standard (29 CFR 1910.134).

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

OSHA is requesting to increase its current burden hours from 20,558 to 22,381 hours, a total increase of 1,823 hours. Although the cost of exposure monitoring sampling increased slightly from \$19 to \$20, there was a \$14,976 increase in the overall cost of sampling (from \$79,344 to \$94,320). Further, although the cost of a medical exam increased from \$175 to \$187, there was a \$976,550 increase in the overall cost of medical exams (from \$2,369,850 to \$2,848,384), as a result of the increase in the number of medical exams.

Type of Review: Extension of a currently approved collection.

Title: Cotton Dust Standard (29 CFR 1910.1043).

OMB Control Number: 1218-0061.

Affected Public: Business or other for-profits.

Number of Respondents: 257.

Frequency of Responses: Annually; semi-annually; on occasion.

Total Responses: 59,718.

Average Time per Response: Varies from 5 minutes (.08 hour) for a secretary to maintain a record to 2 hours to conduct exposure monitoring.

Estimated Total Burden Hours: 22,381.

Estimated Cost (Operation and Maintenance): \$2,942,704.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows:

(1) Electronically at <http://www.regulations.gov>, which is the Federal eRulemaking Portal; (2) by facsimile (fax); or (3) by hard copy. All comments, attachments, and other material must identify the Agency name and the OSHA docket number for the ICR (Docket No. OSHA-2011-0194). You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so the Agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693-2350, (TTY) (877) 889-5627).

Comments and submissions are posted without change at <http://www.regulations.gov>. Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and date of birth. Although all submissions are listed in the <http://www.regulations.gov> index, some information (e.g., copyrighted material) is not publicly available to read or download from this Web site.

All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the <http://www.regulations.gov> Web site to submit comments and access the docket is available at the Web site's "User Tips" link. Contact the OSHA Docket Office for information about materials not available from the Web site and for assistance in using the Internet to locate docket submissions.

V. Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 et seq.) and Secretary of Labor's Order No. 1-2012 (77 FR 3912).

Signed at Washington, DC, on November 7, 2014.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2014-26869 Filed 11-12-14; 8:45 am]

BILLING CODE 4510-26-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA-2011-0195]

Acrylonitrile Standard; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning its proposal to extend OMB approval of the information collection requirements specified by the Acrylonitrile Standard (29 CFR 1910.1045).

DATES: Comments must be submitted (postmarked, sent, or received) by January 12, 2015.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at <http://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages you may fax them to the OSHA Docket Office at (202) 693-1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA-2011-0195, U.S. Department of Labor, Occupational Safety and Health Administration, Room N-2625, 200 Constitution Avenue NW., Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m. to 4:45 p.m., e.t.

Instructions: All submissions must include the Agency name and the OSHA docket number (OSHA-2011-0195) for the Information Collection Request (ICR). All comments, including any personal information you provide, are placed in the public docket without change, and may be made available

online at <http://www.regulations.gov>. For further information on submitting comments see the "Public Participation" heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

Docket: To read or download comments or other material in the docket, go to <http://www.regulations.gov> or the OSHA Docket Office at the address above. All documents in the docket (including this **Federal Register** notice) are listed in the <http://www.regulations.gov> index; however, some information (e.g., copyrighted material) is not publicly available to read or download from the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You may also contact Theda Kenney at the address below to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT:

Theda Kenney or Todd Owen, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, Room N-3609, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693-2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (i.e., employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accord with the Paperwork Reduction Act of 1995 (PRA-95) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the OSH Act) (29 U.S.C. 651 et seq.) authorizes information collection by employers as necessary or appropriate for enforcement of the Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of efforts in obtaining information (29 U.S.C. 657).

The information collection requirements specified in the Acrylonitrile (AN) Standard protect

workers from the adverse health effects that may result from their exposure to AN. The major information collection requirements of the AN Standard include notifying workers of their AN exposures, implementing a written compliance program, providing examining physicians with specific information, ensuring that workers receive a copy of their medical examination results, maintaining workers exposure monitoring and medical records for specific periods, and providing access to these records by OSHA, the National Institute for Occupational Safety and Health, the affected workers, and designated representatives.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

OSHA is requesting that OMB extend its approval of the information collection requirements contained in the Acrylonitrile Standard (29 CFR 1910.1045).

OSHA is requesting an adjustment decrease in the burden hour total from 2,299 to 1,999 hours, a total decrease of 300 hours as a result of the decreased number of affected establishments based on updated data. There was a slight adjustment of the number of exposure monitoring samples from 864 to 814., but the number of medical exams slightly decreased from 630 to 594, which resulted in a slight cost decrease. The adjustment of the burden hours and costs are shown in detail by provision in the supporting statement.

Type of Review: Extension of a currently approved collection.

Title: Acrylonitrile Standard (29 CFR part 1910.1045).

OMB Control Number: 1218-0126.

Affected Public: Business or other for-profits.

Number of Respondents: 16.

Frequency of Responses: On occasion.

Total Responses: 4,516.

Average Time per Response: Varies from five minutes (.08 hour) to obtain a physician's certificate to 12 hours to develop a compliance program.

Estimated Total Burden Hours: 1,999.

Estimated Cost (Operation and Maintenance): \$144,628.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) electronically at <http://www.regulations.gov>, which is the Federal eRulemaking Portal; (2) by facsimile (fax); or (3) by hard copy. All comments, attachments, and other material must identify the Agency name and the OSHA docket number (Docket No. OSHA-2011-0195) for the ICR. You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so the Agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693-2350, (TTY) (877) 889-5627). Comments and submissions are posted without change at <http://www.regulations.gov>. Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and date of birth. Although all submissions are listed in the <http://www.regulations.gov> index, some information (e.g., copyrighted material) is not publicly available to read or download from this Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the <http://www.regulations.gov> Web site to submit comments and access the docket is available at the Web site's "User Tips" link. Contact the OSHA Docket Office for information about materials not available from the Web site, and for assistance in using the Internet to locate docket submissions.

V. Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 et seq.) and Secretary of Labor's Order No. 1–2012 (77 FR 3912).

Signed at Washington, DC, on November 7, 2014.

David Michaels,

Assistant Secretary of Labor, for Occupational Safety and Health.

[FR Doc. 2014–26868 Filed 11–12–14; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR**Occupational Safety and Health Administration**

[Docket No. OSHA–2011–0190]

Shipyard Employment Standards; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning its proposal to extend OMB approval of the information collection requirements contained in the Shipyard Employment Standards of Subpart G—Gear and Equipment for Rigging and Materials Handling (29 CFR 1915.112(a)(1), 29 CFR 1915.112(b)(1)(i), 29 CFR 1915.112(c)(1)(i), 29 CFR 1915.112(c)(2), 29 CFR 1915.113(a)(1), 29 CFR 1915.113(b)(1) and 29 CFR 1915.115(c)) and Subpart K—Portable, Unfired Pressure Vessels, Drums and Containers, Other than Ship's Equipment (29 CFR 1915.172(d)). The purpose of the collection of information (paperwork) provisions of the Standards is to reduce workers' risk of death or serious injury by ensuring that equipment has been tested and is in safe operating condition.

DATES: Comments must be submitted (postmarked, sent, or received) by January 12, 2015.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at <http://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer

than 10 pages you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA–2011–0190, U.S. Department of Labor, Occupational Safety and Health Administration, Room N–2625, 200 Constitution Avenue NW., Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m. to 4:45 p.m., e.t.

Instructions: All submissions must include the Agency name and the OSHA docket number (OSHA–2011–0190) for the Information Collection Request (ICR). All comments, including any personal information you provide, are placed in the public docket without change and may be made available online at <http://www.regulations.gov>. For further information on submitting comments, see the "Public Participation" heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

Docket: To read or download comments or other material in the docket, go to <http://www.regulations.gov> or the OSHA Docket Office at the address above. All documents in the docket (including this **Federal Register** notice) are listed in the <http://www.regulations.gov> index; however, some information (e.g., copyrighted material) is not publicly available to read or download from the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You may also contact Theda Kenney at the address below to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Theda Kenney or Todd Owen, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, Room N–3609, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:**I. Background**

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (i.e., employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accord with the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3506(c)(2)(A)).

This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the OSH Act) (29 U.S.C. 651 et seq.) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of efforts in obtaining information (29 U.S.C. 657).

Manila rope and manila-rope slings (paragraph 1915.112(a)(1))—The employer must ensure that manila rope and manila-rope slings have permanently affixed and legible identification markings as prescribed by the manufacturer that indicate the recommended safe working load for the type(s) of hitch(es) used, the angle upon which it is based, and the number of legs if more than one.

Wire rope and wire-rope slings (paragraph 1915.112(b)(1)(i))—The employer must ensure that wire rope and wire-rope slings have permanently affixed and legible identification markings as prescribed by the manufacturer that indicate the recommended safe working load for the type(s) of hitch(es) used, the angle upon which it is based, and the number of legs if more than one.

Chain and chain slings (paragraph 1915.112(c)(1)(i))—The employer must ensure that chain and chain slings have permanently affixed and legible identification markings as prescribed by the manufacturer that indicate the recommended safe working load for the type(s) of hitch(es) used, the angle upon which it is based, and the number of legs if more than one.

Chain and chain slings (paragraph 1915.112(c)(2))—The employer shall visually inspect all sling chains, including end fastenings, before being used on the job, as well as every three months. The inspection shall include inspection for wear, defective welds, deformation and increase in length or stretch. Each chain shall bear an indication of the month in which it was thoroughly inspected.

Shackles (paragraph 1915.113(a)(1))—The employer must ensure that shackles have permanently

affixed and legible identification markings as prescribed by the manufacturer that indicate the recommended safe working load.

Test Records for Hooks (paragraph 1915.113(b)(1))—This paragraph requires that the manufacturer's recommendations be followed in determining the safe working loads of the various sizes and types of hooks. If the manufacturer's recommendations are not available, the hook must be tested to twice the intended safe working load before it is initially put into use. The employer must maintain and keep readily available a certification record which includes the date of such test, the signature of the person who performed the test, and an identifier for the hook which was tested.

The records are used to assure that equipment has been properly tested. The records also provide the most efficient means for the compliance officers to determine that an employer is complying with the Standard.

Mobile Crawler or Truck Cranes Used on a Vessel (paragraph 1915.115(c))—This paragraph requires that the maximum manufacturer's rated safe working loads for the various working radii of the boom and the maximum and minimum radii at which the boom may be safely used with and without outriggers shall be conspicuously posted near the controls and shall be visible to the operator.

Examination and Test Records for Unfired Pressure Vessels (paragraph 1915.172(b) and (d))—This paragraph requires that portable, unfired pressure vessels not built to the requirements of the American Society of Mechanical Engineers Boiler and Pressure Vessel Code, Section VIII, Rules for Construction of Unfired Pressure Vessels, 1963 be examined *quarterly* by a competent person and subjected to a *yearly* hydrostatic pressure test. A certification record of such examinations and tests shall be maintained.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and

- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

OSHA is proposing to increase the existing burden hour estimate for the collection of information requirements specified by the Standards from 3,162 hours to 9,773 hours, a total increase of 6,611 hours. In this ICR, the scope of the maritime standards in 29 CFR 1915 for slings, shackles, and hooks are based on the Final Economic Analysis for the Final Rule revising subpart F of 29 CFR part 1915 prepared by OSHA's Office of Regulatory Analysis. As a result of the Final Rule, the revision of the standard applies to all shipyard employment which is defined in § 1915.4(i) as ship repairing, shipbuilding, shipbreaking, and related employment. Also, upon further analysis, the Agency identified two new collections of information contained in the Standard under paragraphs §§ 1915.112(c)(2) and 1915.115(c)(1). The Agency will summarize any comments submitted in response to this notice and will include this summary in its request to OMB.

Type of Review: Extension of a currently approved collection.

Title: Shipyard Employment Standards (29 CFR part 1915).

OMB Number: 1218-0220.

Affected Public: Business or other for-profits; Not-for-profit organizations; Federal Government; State, Local, or Tribal Government.

Number of Respondents: 2,759.

Frequency of Response: On occasion.

Average Time per Response: Varies from 2 minutes (.03 hour) to maintain a certification record to 35 minutes (.58 hour) to obtain certain information from a manufacturer.

Estimated Total Burden Hours: 9,773.

Estimated Cost (Operation and Maintenance): \$0.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at <http://www.regulations.gov>, which is the Federal eRulemaking Portal; (2) by facsimile (fax); or (3) by hard copy. All comments, attachments, and other material must identify the Agency name and the OSHA docket number for the ICR (Docket No. OSHA-2011-0190). You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an

electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the docket number, so the Agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693-2350, (TTY) (877) 889-5627).

Comments and submissions are posted without change at <http://www.regulations.gov>. Therefore, OSHA cautions commenters about submitting personal information, such as social security numbers and date of birth. Although all submissions are listed in the <http://www.regulations.gov> index, some information (e.g., copyrighted material) is not publicly available to read or download from this Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the <http://www.regulations.gov> Web site to submit comments and access the docket is available at the Web site's "User Tips" link. Contact the OSHA Docket Office for information about materials not available from the Web site, and for assistance in using the Internet to locate docket submissions.

V. Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 1-2012 (77 FR 3912).

Signed at Washington, DC, on November 7, 2014.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2014-26870 Filed 11-12-14; 8:45 am]

BILLING CODE 4510-26-P

DEPARTMENT OF LABOR**Occupational Safety and Health Administration****[Docket No. OSHA–2014–0001]****National Advisory Committee on Occupational Safety and Health (NACOSH)****AGENCY:** Occupational Safety and Health Administration (OSHA), Labor.**ACTION:** Announcement of a meeting of NACOSH.**SUMMARY:** NACOSH will meet December 10, 2014, in Washington, DC.**DATES:** *NACOSH meeting:* NACOSH will meet from 9 a.m. to 5 p.m., Wednesday, December 10, 2014.

Comments, requests to speak, speaker presentations, and requests for special accommodations: You must submit (postmark, send, transmit) comments, requests to address NACOSH, speaker presentations (written or electronic), and requests for special accommodations for the NACOSH meeting by December 2, 2014.

ADDRESSES: *NACOSH meeting:* NACOSH will meet in Room N–4437 A/B/C, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210.

Submission of comments and requests to speak: You may submit comments and requests to speak at the NACOSH meeting, identified by docket number for this **Federal Register** notice (Docket No. OSHA–2014–0001), by one of the following methods:

Electronically: You may submit materials, including attachments, electronically at <http://www.regulations.gov>, the Federal eRulemaking Portal. Follow the online instructions for making submissions.

Facsimile: If your submission, including attachments, does not exceed 10 pages, you may fax it to the OSHA Docket Office at (202) 693–1648.

Regular mail, express mail, hand delivery, or messenger/courier service (hard copy): You may submit your materials to the OSHA Docket Office, Docket No. OSHA–2014–0001, Room N–2625, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2350 (TTY (887) 889–5627). OSHA's Docket Office accepts deliveries (hand deliveries, express mail, and messenger/courier service) during normal business hours, 8:15 a.m. to 4:45 p.m. e.t., weekdays.

Requests for special accommodations: Please submit requests for special accommodations to attend the NACOSH

meeting by email, telephone, or hard copy to Ms. Gretta Jameson, OSHA, Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–1999 (TTY (887) 889–5627); email jameson.gretta@dol.gov.

Instructions: Your submissions must include the Agency name and docket number for this **Federal Register** notice (Docket No. OSHA–2014–0001). Due to security-related procedures, submissions by regular mail may experience significant delays. Please contact the OSHA Docket Office for information about security procedures for making submissions by hand delivery, express delivery, or messenger/courier service. For additional information about submitting comments and requests to speak, see the **SUPPLEMENTARY INFORMATION** section of this notice.

OSHA will post in the public docket, without change, any comments, requests to speak, and speaker presentations, including any personal information that you provide. Therefore, OSHA cautions interested parties about submitting personal information such as Social Security numbers and birthdates.

FOR FURTHER INFORMATION CONTACT:

For press inquiries: Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, Room N–3647, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–1999 (TTY (877) 889–5627); email meilinger.francis2@dol.gov.

For general information: Ms. Michelle Walker, Director, OSHA Technical Data Center, Directorate of Technical Support and Emergency Management, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2350 (TTY (877) 889–5627); email walker.michelle@dol.gov.

SUPPLEMENTARY INFORMATION: NACOSH will meet December 10, 2014, in Washington, DC. Some NACOSH members may attend electronically. NACOSH meetings are open to the public.

NACOSH was established by Section 7(a) of the Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651, 656) to advise, consult with and make recommendations to the Secretary of Labor and the Secretary of Health and Human Services on matters relating to the administration of the OSH Act. NACOSH is a continuing advisory committee of indefinite duration.

NACOSH operates in accordance with the Federal Advisory Committee Act

(FACA) (5 U.S.C. App. 2), its implementing regulations (41 CFR part 102–3), and OSHA's regulations on NACOSH (29 CFR part 1912a).

The tentative agenda for the NACOSH meeting includes:

- Remarks from the Assistant Secretary of Labor for Occupational Safety and Health;
- Remarks from the Director of the National Institute for Occupational Safety and Health;
- Updates on Ebola activities;
- Request for information (RFI) on Chemical Management and Permissible Exposure Limits (PELs); and
- Protecting Temporary Workers: Recommended Practices.

OSHA transcribes and prepares detailed minutes of NACOSH meetings. OSHA posts the transcripts and minutes in the public docket along with written comments, speaker presentations, and other materials submitted to NACOSH or presented at NACOSH meetings.

Public Participation, Submissions and Access to Public Record

NACOSH meetings: NACOSH meetings are open to the public. Individuals attending NACOSH meetings at the U.S. Department of Labor must enter the building at the Visitors' Entrance at 3rd and C Streets NW., and pass through building security. Attendees must have valid government-issued photo identification (e.g., driver's license) to enter the building. For additional information about building security measures for attending NACOSH meetings, please contact Ms. Jameson (see **ADDRESSES** section).

Individuals requesting special accommodations to attend the NACOSH meeting should contact Ms. Jameson.

Submission of comments: You may submit comments using one of the methods listed in the **ADDRESSES** section. Your submission must include the Agency name and Docket number for this NACOSH meeting (Docket No. OSHA–2014–0001). OSHA will provide copies of your submissions to NACOSH members.

Because of security-related procedures, submissions by regular mail may experience significant delays. For information about security procedures for submitting materials by hand delivery, express mail, and messenger/courier service, please contact the OSHA Docket Office.

Requests to speak and speaker presentations: If you want to address NACOSH at the meeting you must submit a request to speak, as well as any written or electronic presentation, by December 2, 2014, using one of the

methods listed in the **ADDRESSES** section. Your request must state:

- The amount of time requested to speak;
 - The interest you represent (e.g., business, organization, affiliation), if any; and
 - A brief outline of the presentation.
- PowerPoint presentations and other electronic materials must be compatible with PowerPoint 2010 and other Microsoft Office 2010 formats. The NACOSH Chair may grant requests to address NACOSH as time and circumstances permit.

Public docket of NACOSH meetings: OSHA places comments, requests to speak, and speaker presentations, including any personal information you provide, in the public docket, without change. Those documents also may be available online at <http://www.regulations.gov>. Therefore, OSHA cautions you about submitting certain personal information such as Social Security numbers and birthdates.

OSHA also places in the public docket meeting transcripts, meeting minutes, documents presented at the NACOSH meeting, and other documents pertaining to NACOSH meetings. These documents may be available online at <http://www.regulations.gov>.

Access to the public record of NACOSH meetings: To read or download documents in the public docket, go to Docket No. OSHA-2014-0001 at <http://www.regulations.gov>. The index of that Web page lists all of the documents in the public record for this meeting; however, some documents (e.g., copyrighted materials) are not publicly available through that Web page. All documents in the public record, including materials not available through <http://www.regulations.gov>, are available for inspection in the OSHA Docket Office. Please contact the OSHA Docket Office for assistance in making submissions to, or obtaining materials from, the public docket.

Electronic copies of this **Federal Register** notice are available at <http://www.regulations.gov>. This notice, as well as news releases and other relevant information, are also available on OSHA's Web page at <http://www.osha.gov>.

Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice under the authority granted by 29 U.S.C. 656; 5 U.S.C. App. 2; 29 CFR part 1912a; 41 CFR part 102-3; and Secretary of Labor's Order No. 1-2012 (77 FR 3912 (January 25, 2012)).

Signed at Washington, DC, on November 6, 2014.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2014-26797 Filed 11-12-14; 8:45 am]

BILLING CODE 4510-26-P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (14-113)]

NASA Advisory Council; Human Exploration and Operations Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92-463, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Human Exploration and Operations Committee of the NASA Advisory Council.

DATES: Tuesday, December 2, 2014, 10:00 a.m. to 6:00 p.m.; and Wednesday, December 3, 2014, 8:00 a.m. to 4:30 p.m., Local Time.

ADDRESSES: NASA Headquarters, 300 E Street SW., Room 9H40, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Dr. Bette Siegel, Human Exploration and Operations Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358-2245, or bette.siegel@nasa.gov.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. This meeting is also available telephonically and by WebEx. Any interested person may call the USA toll free conference call number 1-888-469-0647 or toll number 1-203-827-7016, pass code 5106584, to participate in this meeting by telephone. The WebEx link is <https://nasa.webex.com/>, the meeting number is 993 284 327, and the password is December2-3!

The agenda for the meeting includes the following topics:

- Joint Session with Science Committee of the NASA Advisory Council
- Status of the International Space Station Focus on Utilization and International Cooperation
- Status of the NASA Human Exploration Operations Mission Directorate
- Radiation Environment and Countermeasures for Human Exploration to Mars

- NASA Human Exploration and Operations Mission Directorate/NASA Science Mission Directorate Joint Activities
- Evolvable Mars Campaign
- Asteroid Redirect Mission and Sustainable Human Exploration
- Lessons Learned from Commercial Orbital Transportation Services
- Research Subcommittee Briefing

Attendees will be requested to sign a register and to comply with NASA Headquarters security requirements, including the presentation of a valid picture ID before receiving access to NASA Headquarters. Foreign nationals attending this meeting will be required to provide a copy of their passport and visa in addition to providing the following information no less than 10 working days prior to the meeting: full name; gender; date/place of birth; citizenship; passport information (number, country, telephone); visa information (number, type, expiration date); employer/affiliation information (name of institution, address, country, telephone); title/position of attendee, to Dr. Bette Siegel via email at bette.siegel@nasa.gov. To expedite admittance, attendees with U.S. citizenship and Permanent Residents (green card holders) are requested to submit their name and affiliation 3 working days prior to the meeting to Dr. Bette Siegel. It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants.

Patricia D. Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2014-26775 Filed 11-12-14; 8:45 am]

BILLING CODE 7510-13-P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (14-111)]

NASA Advisory Council; Technology, Innovation and Engineering Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92-463, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Technology, Innovation and Engineering Committee of the NASA Advisory Council. This meeting will be held for the purpose of soliciting, from

the scientific community and other persons, scientific and technical information relevant to program planning.

DATES: Thursday, December 4, 2014, 8:00 a.m. to 5:00 p.m.; Local Time.

ADDRESSES: NASA Headquarters, Room MIC 6A, 300 E Street SW., Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Mr. Mike Green, Space Technology Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358-4710, or g.m.green@nasa.gov.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the capacity of the room. This meeting is also available telephonically and online via WebEx. Any interested person may call the USA toll free conference number 844-467-6272, passcode 102421, to participate in this meeting by telephone. The WebEx link is <https://nasa.webex.com/>, the meeting number is 999 401 003, and the password is "Technology14\$".

The agenda for the meeting includes the following topics:

- NASA Office of the Chief Technologist Update
- Briefing and Update on the Technology Demonstration Missions Program
- NASA Space Technology Mission Directorate Update
- Briefing and Update of NASA's Advance Exploration Systems Program
- NASA Office of the Chief Engineer Update
- Update on NASA's Future Workforce Diversity Efforts
- Discussion of Committee Recommendation on Technology Infusion into Future Science Missions

Attendees will be requested to sign a register and to comply with NASA Headquarters security requirements, including the presentation of a valid picture ID, before receiving access to NASA Headquarters. Foreign nationals attending this meeting will be required to provide a copy of their passport and visa in addition to providing the following information no less than 10 working days prior to the meeting: full name; gender; date/place of birth; citizenship; passport information (number, country, expiration date); visa information (number, type, expiration date); employer/affiliation information (name of institution, address, country, telephone); title/position of attendee. To expedite admittance, attendees with U.S. citizenship and Permanent Residents (green card holders) can provide full name and citizenship status

3 working days in advance by contacting Ms. Anyah Dembling via email at anyah.b.dembling@nasa.gov or by telephone at (202) 358-5195. It is imperative that this meeting be held on this date to accommodate the scheduling priorities of the key participants.

Patricia D. Rausch,

*Advisory Committee Management Officer,
National Aeronautics and Space Administration.*

[FR Doc. 2014-26773 Filed 11-12-14; 8:45 am]

BILLING CODE 7510-13-P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (14-112)]

National Space-Based Positioning, Navigation, and Timing (PNT) Advisory Board; Meeting

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92-463, as amended, and the President's 2004 U.S. Space-Based Positioning, Navigation, and Timing (PNT) Policy, the National Aeronautics and Space Administration (NASA) announces a meeting of the National Space-Based Positioning, Navigation, and Timing (PNT) Advisory Board.

DATES: Wednesday, December 10, 2014, 9:00 a.m. to 5:00 p.m.; and Thursday, December 11, 2014, 9:00 a.m. to 12:00 p.m., Local Time.

ADDRESSES: The Omni Shoreham Hotel, Hampton Ballroom, 2500 Calvert Street NW., Washington, DC 20008.

FOR FURTHER INFORMATION CONTACT: Mr. James J. Miller, Human Exploration and Operations Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358-4417, fax (202) 358-4297, or jj.miller@nasa.gov.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. Visitors will be requested to sign a visitor's register.

The agenda for the meeting includes the following topics:

- Examine emerging trends and requirements for PNT services in U.S. and international arenas through PNT Board technical assessments.
- Update on U.S. Space-Based Positioning, Navigation and Timing (PNT) Policy and Global Positioning System (GPS) modernization.
- Prioritize current and planned GPS capabilities and services while assessing

future PNT architecture alternatives with a focus on affordability.

- Examine methods in which to Protect, Toughen, and Augment (PTA) access to GPS/Global Navigation Satellite System (GNSS) services in key domains for multiple user sectors.
- Assess economic impacts of GPS on the United States and in select international regions, with a consideration towards effects of potential PNT service disruptions if radio spectrum interference is introduced.

- Explore opportunities for enhancing the interoperability of GPS with other emerging international GNSS.

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants.

Patricia D. Rausch,

*Advisory Committee Management Officer,
National Aeronautics and Space Administration.*

[FR Doc. 2014-26774 Filed 11-12-14; 8:45 am]

BILLING CODE 7510-13-P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Arts Advisory Panel Meeting

AGENCY: National Endowment for the Arts, National Foundation on the Arts and Humanities.

ACTION: Notice of meeting.

SUMMARY: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), as amended, notice is hereby given that 21 meetings of the Arts Advisory Panel to the National Council on the Arts will be held by teleconference from the National Endowment for the Arts, Constitution Center, 400 7th St. SW., Washington, DC 20506 as follows (all meetings are Eastern time and ending times are approximate):

Music (application review): This meeting will be closed.

Dates: November 13, 2014. 12:00 p.m. to 2:00 p.m.

Music (application review): This meeting will be closed.

Dates: November 13, 2014. 3:00 p.m. to 5:00 p.m.

Music (application review): This meeting will be closed.

Dates: November 14, 2014. 1:00 p.m. to 3:00 p.m.

Media Arts (application review): This meeting will be closed.

Dates: November 17, 2014. 2:00 p.m. to 4:30 p.m.

Media Arts (application review): This meeting will be closed.

Dates: November 18, 2014. 2:00 p.m. to 4:30 p.m.

Theater & Musical Theater (application review): This meeting will be closed.

Dates: November 18, 2014. 12:00 p.m. to 2:00 p.m.

Theater & Musical Theater (application review): This meeting will be closed.

Dates: November 18, 2014. 3:00 p.m. to 5:00 p.m.

Opera (application review): This meeting will be closed.

Dates: November 19, 2014. 12:00 p.m. to 1:30 p.m.

Opera (application review): This meeting will be closed.

Dates: November 19, 2014. 3:00 p.m. to 4:30 p.m.

Presenting & Multidisciplinary Works (application review): This meeting will be closed.

Dates: November 19, 2014. 2:00 p.m. to 4:00 p.m.

Arts Education (application review): This meeting will be closed.

Dates: November 20, 2014. 1:30 p.m. to 3:30 p.m.

Folk & Traditional Arts (application review): This meeting will be closed.

Dates: November 20, 2014. 2:00 p.m. to 4:00 p.m.

Local Arts Agencies (application review): This meeting will be closed.

Dates: November 20, 2014. 1:00 p.m. to 3:00 p.m.

Local Arts Agencies (application review): This meeting will be closed.

Dates: November 20, 2014. 3:30 p.m. to 5:30 p.m.

Theater & Musical Theater (application review): This meeting will be closed.

Dates: November 20, 2014. 12:00 p.m. to 2:00 p.m.

Theater & Musical Theater (application review): This meeting will be closed.

Dates: November 20, 2014. 3:00 p.m. to 5:00 p.m.

Folk & Traditional Arts (application review): This meeting will be closed.

Dates: November 21, 2014. 2:00 p.m. to 4:00 p.m.

Visual Arts (application review): This meeting will be closed.

Dates: November 24, 2014. 11:30 a.m. to 2:00 p.m.

Visual Arts (application review): This meeting will be closed.

Dates: November 24, 2014. 2:30 p.m. to 5:00 p.m.

Visual Arts (application review): This meeting will be closed.

Dates: November 25, 2014. 11:30 a.m. to 2:00 p.m.

Visual Arts (application review): This meeting will be closed.

Dates: November 25, 2014. 2:30 p.m. to 5:00 p.m.

FOR FURTHER INFORMATION CONTACT:

Further information with reference to these meetings can be obtained from Ms. Kathy Plowitz-Worden, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC 20506; plowitzk@arts.gov, or call 202/682-5691.

SUPPLEMENTARY INFORMATION: The closed portions of meetings are for the purpose of Panel review, discussion, evaluation, and recommendations on financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency. In accordance with the determination of the Chairman of February 15, 2012, these sessions will be closed to the public pursuant to subsection (c)(6) of section 552b of Title 5, United States Code.

Dated: November 6, 2014.

Kathy Plowitz-Worden,

Panel Coordinator, National Endowment for the Arts.

[FR Doc. 2014-26793 Filed 11-12-14; 8:45 am]

BILLING CODE 7537-01-P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Submission for OMB Review; Comment Request

The National Endowment for the Arts, on behalf of the Federal Council on the Arts and the Humanities, has submitted the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chapter 35). Copies of this ICR, with applicable supporting documentation, may be obtained at reginfo.gov.

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the National Endowment for the Arts, Office of Management and Budget, Room 10235, Washington, DC 20503 (202/395-4718), within thirty days of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

— Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

— Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; — Enhance the quality, utility and clarity of the information to be collected; and — Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

SUPPLEMENTARY INFORMATION: The Endowment requests the review of its application guidelines. This entry is issued by the Endowment and contains the following information: (1) The title of the form; (2) how often the required information must be reported; (3) who will be required or asked to report; (4) what the form will be used for; (5) an estimate of the number of responses; (6) the average burden hours per response; (7) an estimate of the total number of hours needed to prepare the form. This entry is not subject to 44 U.S.C. § 3504(h).

Agency: National Endowment for the Arts.

Title: Application for Indemnification. *OMB Number:* 3135-0123.

Frequency: renewed every three years.

Affected Public: Non-profit, tax exempt organizations, and governmental units.

Number of Respondents: 19 per year.

Estimated Time per Respondent: 40 hours.

Estimate Cost per Respondent: \$2,025.

Total Burden Hours: 760.

Total Annualized Capital/Startup Costs: 0.

Total Annual Costs (Operating/Maintaining Systems or Purchasing Services): \$97,000.

Description: This application form is used by non-profit, tax-exempt organizations (primarily museums), and governmental units to apply to the Federal Council on the Arts and the Humanities (through the National Endowment for the Arts) for indemnification of eligible works of art and artifacts, borrowed from lenders in the United States for exhibition in the United States. The indemnity agreement is backed by the full faith and credit of the United States. In the event of loss or damage to an indemnified object, the Federal Council certifies the validity of the claim and requests payment from Congress. 20 U.S.C. 973 et seq. requires such an application and specifies

information which must be supplied. This statutory requirement is implemented by regulation at 45 CFR ll60.4.

Dated: November 7, 2014.

Kathy Plowitz-Worden,

Panel Coordinator, National Endowment for the Arts.

[FR Doc. 2014-26820 Filed 11-12-14; 8:45 am]

BILLING CODE 7537-01-P

NATIONAL SCIENCE FOUNDATION

National Science Board

The National Science Board's *ad hoc* Committee on Honorary Awards, pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n-5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of a meeting for the transaction of National Science Board business, as follows:

Date and Time: Monday, November 17, 2014 at 11:00 a.m. EST.

Subject Matter: Consideration of nominations for honorary awards.

Status: Closed.

This meeting will be held by teleconference originating at the National Science Board Office, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230.

Please refer to the National Science Board Web site (www.nsf.gov/nsb) for information or schedule updates, or contact: Nadine Lymn, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: (703) 292-7000.

Ann Bushmiller,

NSB Senior Legal Counsel.

[FR Doc. 2014-26806 Filed 11-12-14; 8:45 am]

BILLING CODE 7555-01-P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 31333; 812-14139]

Eaton Vance Management, et al.; Notice of Application

November 6, 2014.

AGENCY: Securities and Exchange Commission ("Commission").

ACTION: Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 ("Act") for an exemption from sections 2(a)(32), 5(a)(1), 22(d) and 22(e) of the Act and rule 22c-1 under the Act, under

sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and (a)(2) of the Act, and under section 12(d)(1)(J) of the Act for an exemption from sections 12(d)(1)(A) and (B) of the Act.

APPLICANTS: Eaton Vance Management ("Eaton Vance"), Eaton Vance ETMF Trust ("ETMF Trust") and Eaton Vance ETMF Trust II ("ETMF Trust II").

SUMMARY: Applicants request an order that permits: (a) Actively managed series of certain open-end management investment companies to issue shares ("Shares") redeemable in large aggregations only ("Creation Units"); (b) secondary market transactions in Shares to occur at the next-determined net asset value ("NAV") plus or minus a market-determined premium or discount ("premium/discount") that may vary during the trading day ("NAV-based Trading"); (c) certain series to pay redemption proceeds, under certain circumstances, more than seven days from the tender of Shares for redemption; (d) certain affiliated persons of the series to deposit securities into, and receive securities from, the series in connection with the purchase and redemption of Creation Units; (e) certain registered management investment companies and unit investment trusts outside of the same group of investment companies as the series to acquire Shares; and (f) certain series to create and redeem Shares in kind in a master-feeder structure.

DATES: The application was filed on March 27, 2013 and amended on September 12, 2013, January 23, 2014, September 15, 2014, and September 25, 2014.

HEARING OR NOTIFICATION OF HEARING:

An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on December 1, 2014, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0-5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street

NE., Washington, DC 20549-1090. Applicants: Frederick S. Marius, Esq., Eaton Vance Management, Two International Place, Boston, MA 02110.

FOR FURTHER INFORMATION CONTACT: Jean E. Minarick, Senior Counsel, Daniele Marchesani, Branch Chief or Dalia Osman Blass, Assistant Chief Counsel, at (202) 551-6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at <http://www.sec.gov/search/search.htm> or by calling (202) 551-8090.

Applicants

1. ETMF Trust and ETMF Trust II (each, a "Trust" and, together the "Trusts") will be registered as open-end management investment companies under the Act and are business trusts organized under the laws of Massachusetts. ETMF Trust and ETMF Trust II will initially offer ten and eight series, respectively (the "Initial ETMFs"). Each ETMF (as defined below) will invest in securities and other assets selected to pursue the ETMF's investment objective ("Portfolio Positions").¹

2. Eaton Vance, a Massachusetts business trust, will serve as investment adviser to the Initial ETMFs. An Adviser (as defined below) will serve as investment adviser to each ETMF. Eaton Vance is, and any other Adviser will be, registered as an investment adviser under the Investment Advisers Act of 1940 ("Advisers Act"). The Adviser may retain one or more subadvisers (each a "Subadviser") to manage the portfolios of the ETMFs (as defined below). Any Subadviser will be registered, or not subject to registration, under the Advisers Act.

Applicants' Proposal

3. Applicants seek an exemptive order that would permit them to offer

¹ If an ETMF (or, in the case of an ETMF Feeder (as defined below), its Master Fund (as defined below)) invests in derivatives, then (a) the board of trustees ("Board") of the ETMF will periodically review and approve the ETMF's (or, in the case of an ETMF Feeder, its Master Fund's) use of derivatives and how the ETMF's Adviser assesses and manages risk with respect to the ETMF's (or, in the case of an ETMF Feeder, its Master Fund's) investment adviser's use of derivatives and (b) the ETMF's disclosure of its (or in the case of an ETMF Feeder, its Master Fund's) use of derivatives in its offering documents and periodic reports will be consistent with relevant Commission and staff guidance.

exchange-traded managed funds, a new kind of registered investment company that is a hybrid between traditional mutual funds and exchange-traded funds ("exchange-traded managed funds" or ETMFs, as defined below).² Like exchange-traded funds ("ETFs"), ETMFs would: List and trade on a national securities exchange, as defined in section 2(a)(26) of the Act ("Exchange"); directly issue and redeem Shares only in Creation Units; impose fees on Creation Units issued and redeemed to Authorized Participants (as defined below) to offset the related costs to the ETMFs; and primarily utilize in-kind transfers of Portfolio Positions in issuing and redeeming Creation Units. Like mutual funds, ETMFs would be bought and sold at prices linked to NAV and would seek to maintain the confidentiality of their current Portfolio Positions. Applicants have structured the product in this manner to provide certain cost and tax efficiencies of ETFs to investors, while maintaining the confidentiality of current Portfolio Positions.³

4. Applicants request that the order apply to the Initial ETMFs and any future series of the Trusts as well as any other open-end management investment companies or series thereof that: (a) Are advised by Eaton Vance or an entity controlling, controlled by, or under common control with Eaton Vance (Eaton Vance and each such other entity, and any successor thereto, included in the term "Adviser");⁴ and (b) comply with the terms and conditions of the requested order ("Future ETMFs").⁵ An ETMF would

offer its Shares in Creation Units only; individual Shares would trade on an Exchange using NAV-based Trading. The Initial ETMFs and the Future ETMFs together are the "ETMFs."⁶

A. Exchange Trading and NAV-Based Trading

5. Shares would be listed and traded on an Exchange ("Listing Exchange").⁷ Shares would trade throughout the day at NAV⁸ plus or minus a premium/discount that may vary during the trading day.⁹ This premium/discount (solely by way of example, +\$0.20/Share, – \$0.30/Share) would be quoted by Market Makers in Shares.¹⁰ Although

Adviser") advising a trust that intends to launch new series that will operate as exchange-traded managed funds (the Licensed Adviser and such trust together, the "Future Applicants"). Future Applicants will apply for a separate exemptive order that incorporates by reference all the terms and conditions of this requested order and any amendments thereto. Therefore, any future amendments to the requested order would become part of any separate exemptive orders granted to Future Applicants. Any separate order granted to Future Applicants also would contain a condition that the Future Applicants must ensure that they comply with any terms and conditions of the requested order and any amendments thereto.

⁶ All entities that currently intend to rely on the order are named as applicants. Any other entity that relies on the order in the future will comply with the terms and conditions of the requested order.

⁷ Applicants currently expect that The NASDAQ Stock Market LLC ("Nasdaq") will be the Listing Exchange for the Initial ETMFs. One or more member firms of the Listing Exchange will act as market maker ("Market Maker") and maintain a market for Shares trading on the Listing Exchange.

⁸ An ETMF's NAV will be determined at the end of each Business Day. A "Business Day" is any day the ETMF is open, including any day when it satisfies redemption requests as required by section 22(e) of the Act. ETMFs may compute their NAV more than once each Business Day or once daily at times other than 4:00 p.m. ET, consistent with rule 22c-1 under the Act.

⁹ Unlike other exchange-traded securities, there would not be an absolute dollar amount per Share until the end of the day. Accordingly, prior to the initial operations of ETMFs, the Exchanges and brokers would install systems for the entry of orders to buy and sell shares using NAV-based Trading. Applicants have been working with intermediaries and Nasdaq to ensure they are implementing appropriate operational arrangements to accommodate the unique pricing mechanism of ETMFs (e.g., the convention for reporting the intraday pricing of Shares on the consolidated tape). Applicants have also represented that they would establish and support a robust education program to ensure that investors and the marketplace understand, among other things, how to buy and sell Shares. Applicants would also provide related information in the ETMFs' registration statements, Web site and advertising and marketing materials.

¹⁰ The amount of the premium/discount would depend on market factors, including the balance of supply and demand for Shares among investors, the Transaction Fees (as defined below) and other costs associated with creating and redeeming Creation Units, competition among Market Makers, Share inventory positions, inventory strategies of Market Makers, and the volume of Share trading. Premiums/discounts on market transactions in Shares are not sales charges, and therefore would

Share prices would be quoted throughout the trading day relative to NAV (solely by way of example, NAV+\$0.20/share, NAV – \$0.30/share), there would not be a fixed relationship between Share trading prices and their NAVs. For each trade, the premium/discount (which may be zero) would be locked in at trade execution and the final transaction price (i.e., NAV plus or minus the premium/discount) would be determined at the end of the Business Day when the ETMF's NAV is calculated.¹¹

6. Accordingly, unlike ETFs, NAV-Based Trading would not offer investors the opportunity to transact intraday at prices based on current (versus end-of-day) determinations of the Shares' value. Instead, like intraday orders to buy or sell shares of mutual funds, an ETMF investor would not know the NAV at the time the order is placed, but the levels of premium/discount would be fully transparent allowing investors to see the execution costs of buying or selling Shares.¹² Market Makers and other dealers, in turn, would compete for transactions in Shares at a profitable premium/discount level.

B. Issuance and Redemption of Creation Units

7. Shares would not be individually redeemable and owners of Shares may acquire those Shares from an ETMF, or tender such shares for redemption to the ETMF, in Creation Units only.¹³ Like ETFs, all orders to purchase Creation Units must be placed with a distributor ("Distributor") that is a broker-dealer registered under the Securities Exchange Act of 1934 ("Exchange Act") by or through a party (an "Authorized Participant") that has entered into a

not be subject to the limitation applicable to sales charges under NASD Conduct Rule 2830 or any other set limitation. Any reference to NASD Conduct Rule 2830 includes any successor or replacement rule that may be adopted by the Financial Industry Regulatory Authority.

¹¹ Transactions involving the purchases and sales of Shares on the Exchange would also be subject to customary brokerage commissions and charges.

¹² Trading prices of Shares would be available intraday through market data services and on the ETMFs' Web site. Quotations, however, would be expressed relative to NAV (solely by way of example, NAV+\$0.20/Share, NAV – \$0.20/Share) rather than as absolute dollar prices like ETF prices. Historical information regarding levels of premiums/discounts also would be available on the ETMFs' Web site.

¹³ In any advertising material that describes the purchase or sale of Creation Units or refers to redeemability there would be an appropriate statement to the effect that Shares are not individually redeemable. The Adviser also would maintain a public Web site disclosing current ETMF information and containing links to the current prospectus and other ETMF documents. The Web site also would include the disclosure required by condition 3 under ETMF Relief.

² In accordance with the conditions to the requested relief, neither the Trusts nor any ETMF would be marketed or otherwise held out as an "open-end investment company," a "mutual fund" or "exchange-traded fund." Instead, each ETMF would be marketed as an "exchange-traded managed fund" or "ETMF."

³ Through in-kind redemptions (as described below), ETMFs would seek to achieve tax efficiencies for its shareholders by avoiding the tax consequences of selling portfolio positions to meet redemption requests in cash. ETMFs could also limit the costs associated with managing inflows and outflows (e.g., trading costs and "cash drag"). By trading on an Exchange, ETMFs would greatly reduce their expenses for transfer agency services. (ETMF shareholders would still be able to receive comparable services through their brokers and would pay only for those services that they elect to receive.) Finally, applicants represent that ETMFs will not charge sales loads or pay any asset-based distribution or service fees.

⁴ For the purposes of the requested order, a "successor" is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization.

⁵ Eaton Vance has obtained patents with respect to certain aspects of ETMF's NAV-based Trading. Applicants anticipate that Eaton Vance or an affiliate thereof will license the patents to other registered investment advisers (each a "Licensed

participant agreement with the Distributor with respect to the creation and redemption of Creation Units.¹⁴

8. Like ETFs, and to keep trading costs low and permit each ETMF to be as fully invested as possible, Shares would be purchased and redeemed in Creation Units and primarily on an in-kind basis. Authorized Participants would be required to purchase Creation Units by making an in-kind deposit of specified instruments (these instruments are referred to, in the case of either a purchase or redemption, as the “Basket Instruments,” and, together as the “Basket”), specified by the ETMF at the beginning of each Business Day and Authorized Participants redeeming their Shares would receive an in-kind transfer of Basket Instruments.¹⁵ The Basket would not necessarily include all Portfolio Positions of the applicable ETMF in order to protect the confidentiality of current Portfolio Positions.

9. Each ETMF would process purchases and redemptions of Creation Units in a manner that would protect the ETMF from any investor who might seek advantageous treatment vis-à-vis other investors. Therefore, each Business Day, the Basket would be constructed in accordance with policies and procedures that: (a) Have been approved by the relevant ETMF’s Board based on a determination that such policies and procedures are in the best interests of the ETMF; and (b) are administered in accordance with rule 38a–1 under the Act by the chief compliance officer designated by the ETMF under that rule. Moreover, the names and quantities of the instruments that constitute the Basket Instruments on a given Business Day would be identical for all purchasers and redeemers of an ETMF’s Creation Units that day, except in certain limited circumstances.¹⁶

¹⁴ An Authorized Participant would be either: (a) A Broker (as defined below) or other participant in the Continuous Net Settlement System of the National Securities Clearing Corporation (“NSCC”), a clearing agency registered with the Commission; or (b) a participant in The Depository Trust Company (“DTC”) (such participant, “DTC Participant”).

¹⁵ ETMFs must comply with the federal securities laws in accepting Basket Instruments and satisfying redemptions with Basket Instruments, including that the Basket Instruments would be sold in transactions that would be exempt from registration under the Securities Act of 1933 (“Securities Act”). In accepting Basket Instruments and satisfying redemptions with Basket Instruments that are restricted securities eligible for resale pursuant to Rule 144A under the Securities Act, ETMFs would comply with the conditions of Rule 144A.

¹⁶ An ETMF’s Basket could vary if the required policies and procedures of the ETMF allowed such differences by permitting an Authorized Participant to deposit cash in lieu of some or all of the Basket

10. To preserve the confidentiality of an ETMF’s trading activities, the Basket would normally not be a pro rata slice of the Portfolio Positions. Instruments being acquired by the ETMF would generally be excluded from the Basket until their purchase is completed and Basket Instruments being sold may not be removed from the Basket until the sale program is substantially completed. Further, when deemed by the Adviser to be in the best interests of an ETMF and its shareholders, other Portfolio Positions would be excluded from the Basket. Whenever Portfolio Positions are excluded from the Basket, the Basket may include proportionately more cash than is in the portfolio. Furthermore, if there is a difference between the NAV attributable to a Creation Unit and the aggregate market value of the Basket exchanged for the Creation Unit, the party conveying a Basket with the lower value would also pay to the other an amount in cash equal to that difference (the “Balancing Amount”).

11. Each Business Day, before the open of trading on the Listing Exchange, the Adviser would cause to be published through the NSCC the names and quantities of the Basket Instruments, as well as the estimated Balancing Amount (if any), for that day. The published Basket would apply until a new Basket is announced on the following Business Day, and there would be no intraday changes to the Basket except to correct errors in the published Basket.¹⁷

Instruments solely because: (a) Such Basket Instruments, in the case of a purchase of a Creation Unit, are not available in sufficient quantity; (b) such Basket Instruments are not eligible for trading by the Authorized Participant or the investor on whose behalf the Authorized Participant is acting; or (c) a holder of Shares of an ETMF investing in foreign instruments would be subject to unfavorable income tax treatment if the holder received redemption proceeds in kind. A “custom order” is any purchase or redemption of Shares made in whole or in part on a cash basis in reliance on clause (a) or (b). An ETMF may also determine, upon receiving a purchase or redemption order from an Authorized Participant, to require the purchase or redemption, as applicable, to be made entirely in cash.

¹⁷ ETMFs would arrange for an independent third party to disseminate every 15 minutes an amount representing, on a per Share basis, the intraday indicative value (“IIV”) of the ETMFs’ Shares throughout the regular trading session of the Listing Exchange each Business Day. An investor may use the IIV to estimate the number of Shares to buy or sell based on the dollar amount the investor wants to transact in. Applicants note that unlike for ETFs, IIVs for ETMFs would not provide pricing signals for market intermediaries or other buyers or sellers of Shares seeking to estimate the difference between the current value of the ETMF’s portfolio and the price at which Shares are currently trading. With ETMF’s NAV-based Trading, market intermediaries and other buyers or sellers of Shares assume no intraday market risk in their Share inventory positions and therefore would not need to estimate any such difference.

12. Any purchasers or redeemers of Creation Units are expected to incur a transaction fee (“Transaction Fee”) to cover the estimated cost to the ETMF of processing the transaction, including the costs of clearance and settlement charged to it by NSCC or DTC, and the estimated trading costs incurred in converting the Basket to the desired Portfolio Positions. The Transaction Fee would be borne only by purchasers and redeemers of Creation Units and would be limited to amounts that have been authorized by the Board and determined appropriate by the Adviser to defray the transaction expenses that would be incurred by an ETMF when an investor purchases or redeems Creation Units.¹⁸ With respect to ETMFs operating in a master-feeder structure (as discussed below), the Transaction Fee may be paid to the Master Fund as a Master Fund Transaction Fee.¹⁹

C. The Role of Market Intermediaries and Portfolio Transparency

13. Applicants assert that in light of NAV-based Trading, daily portfolio transparency is not necessary for ETMFs. Applicants recognize that contemporaneous portfolio holdings disclosure has been viewed as necessary for effective arbitrage and efficient secondary market trading of ETFs.²⁰ In particular, applicants note that in ETF trading, tight bid-ask spreads and narrow premiums/discounts cannot be assured unless Market Makers have

¹⁸ Where an ETMF permits an in-kind purchaser to deposit cash in lieu of depositing one or more Basket Instruments, the purchaser may be assessed a higher Transaction Fee to offset the cost to the ETMF of buying those particular Basket Instruments. In all cases, the Transaction Fee and the Master Fund Transaction Fee (as defined below) will be limited in accordance with the requirements of the Commission applicable to open-end management investment companies offering redeemable securities.

¹⁹ Applicants believe that, to treat investors fairly and consistently, a Master Fund with two or more Feeder Funds should transact with each Feeder Fund on a basis that protects the Master Fund (and, indirectly, other Feeder Funds) against the costs of accommodating the Feeder Fund’s inflows and outflows. In the proposed structure, the Master Fund would accomplish this by imposing a fee (“Master Fund Transaction Fee”) on Feeder Fund inflows and outflows, sized to cover the estimated cost to the Master Fund of, in connection with a sale of its interests, converting the cash and/or other instruments it receives to the desired Portfolio Positions and, in connection with a redemption of its interests, converting Portfolio Positions to cash and/or other instruments to be distributed. The Master Fund Transaction Fee would be applied to all Feeder Funds in the same manner so as to avoid discrimination by the Master Fund among Feeder Funds.

²⁰ See Exchange-Traded Funds, Investment Company Act Release No. 28193 (Mar. 11, 2008) at text following note 29; ICI, 2014 INVESTMENT COMPANY FACT BOOK (2014) (“ICI Fact Book”), at 59, available at www.ici.org/pdf/2014_factbook.pdf.

sufficient knowledge of portfolio holdings to enable them to effectively arbitrage differences between an ETF's market price and its underlying portfolio value and to hedge the intraday market risk they assume as they take inventory positions in connection with their market-making activities. According to applicants, in NAV-based Trading, by contrast, Market Makers do not engage in arbitrage and assume no intraday market risk in their Share inventory positions because all trading prices are linked to NAV.²¹ Applicants state that no intraday market risk means no need for Market Makers to engage in intraday hedging activity, and therefore no associated requirement for current portfolio holdings disclosure to maintain a tight relationship between Share trading prices and NAV.²² Accordingly, applicants maintain that because Share transaction prices would be based on end-of-day NAV, ETMFs can be expected to trade at consistently narrow premiums/discounts to NAV and tight bid-ask spreads even in the absence of full portfolio holdings disclosure.

14. Applicants claim that ETMFs, not being required to provide daily portfolio transparency, have the potential for providing investors with access to a broad range of active strategies in a structure that provides the cost and tax efficiencies and shareholder protections of an ETF.

Requested Exemptive Relief

15. Applicants request an order under section 6(c) of the Act for an exemption

²¹ Applicants state that Market Makers would realize a profit to the extent the premium/discount exceeded their cost in entering into these transactions. Applicants assert that these costs would include, indirectly if the Market Maker is not an Authorized Participant, the Transaction Fees paid to an ETMF and the cost of purchasing or selling the Basket Instruments exchanged with the ETMF. According to applicants, these costs would not include a cost of hedging an intraday position in Shares. Applicants assert that the cost of intermediation would be lower with respect to ETMFs than for ETFs and profits would be relatively more predictable, which should foster intermediary participation in the market for Shares and therefore the competition necessary to limit the levels of the premium/discount.

²² Applicants believe that Market Makers will generally seek to minimize their exposure to price risk in Shares by holding little or no overnight inventory. ETMFs also will have smaller creation unit sizes than ETFs. Applicants also believe that these smaller creation unit sizes will support secondary market trading efficiency by facilitating tighter market maker inventory management because it facilitates closing out positions at the end of each trading day. To the extent that Market Makers hold small positions in Shares overnight, applicants expect them to aggregate such holdings with any other risk positions that they are holding and transact at or near the market close to buy or sell offsetting positions in appropriate, broad-based hedging instruments, such as S&P 500 and other index futures and ETFs.

from sections 2(a)(32), 5(a)(1), 22(d) and 22(e) of the Act and rule 22c-1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act, and under section 12(d)(1)(j) of the Act for an exemption from sections 12(d)(1)(A) and (B) of the Act.

16. Applicants' request for relief is novel only under section 22(d) and rule 22c-1 under the Act with respect to NAV-based Trading. In all other respects, applicants are seeking the same relief that the Commission has previously granted to permit the operation of ETFs. As discussed above, the requested relief would be available to any existing or future investment company that is an ETMF operating in compliance with the terms and conditions of the order and that is advised by an Adviser. In support of future ETMF relief, applicants assert that Future ETMFs raise no legal or policy questions different from those presented by the Initial ETMFs and that the arguments for exemptive relief are equally valid regardless of the type of assets or investment strategy utilized by a specific ETMF. The Commission preliminarily agrees with these assertions.

17. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction, or any class of persons, securities or transactions, from any provisions of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 17(b) of the Act authorizes the Commission to exempt a proposed transaction from section 17(a) of the Act if evidence establishes that the terms of the transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, and the proposed transaction is consistent with the policies of the registered investment company and the general purposes of the Act. Section 12(d)(1)(j) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors.

A. Novel Relief Under Section 22(d) and Rule 22c-1

18. Section 22(d) of the Act, among other things, prohibits a dealer from selling a redeemable security that is

currently being offered to the public by or through a principal underwriter other than at a current public offering price described in the fund's prospectus. Rule 22c-1 under the Act requires open-end funds, their principal underwriters, and dealers in fund shares (and certain others) to sell and redeem fund shares at a price based on the current NAV next computed after receipt of an order to buy or redeem. Together, these provisions are designed to prevent dilution caused by riskless trading schemes, require that shareholders are treated equitably when buying and selling fund shares, and assure an orderly distribution system of investment company shares.

19. Applicants request relief from these provisions to permit NAV-based Trading of Shares. Because of ETMFs' NAV-based Trading, the need for exemptive relief from section 22(d) and rule 22c-1 for ETMFs arises due to the portion of the trading price that is the negotiated amount (*i.e.*, premium/discount).

20. Applicants assert that the concerns underlying section 22(d) of the Act and rule 22c-1 under the Act with respect to pricing are addressed by the NAV-based Trading of Shares. Applicants maintain that while there is little legislative history regarding section 22(d), its provisions, as well as those of rule 22c-1, appear to have been designed to (a) prevent dilution caused by certain riskless-trading schemes by principal underwriters and contract dealers, (b) prevent unjust discrimination or preferential treatment among buyers resulting from sales at different prices, and (c) assure an orderly distribution system of investment company shares by eliminating price competition from brokers offering shares at less than the published sales price and repurchasing shares at more than the published redemption price.

21. Applicants believe that none of these purposes would be thwarted by permitting NAV-based Trading of Shares. Applicants state that NAV-based Trading in Shares would not cause dilution of the shareholders' beneficial interests in ETMFs because secondary market trading in Shares would not involve the ETMF's portfolio. Applicants assert that NAV-Based Trading responds to concerns of unjust price discrimination among purchasers and preserving an orderly distribution of Shares. Shares would trade on an Exchange, a regulated venue, at market-determined premiums/discounts. The current and historical premiums/discounts also would be transparent to investors and intermediaries.

Applicants assert that transparent pricing on an Exchange should foster competition among market intermediaries, which would create downward pressure on intermediaries' profits embedded in the premium/discount and therefore on the total amount of any such premium/discount. Accordingly, applicants contend that the mechanics of the distribution of Shares and competitive market forces on an Exchange would work to limit the premium/discount and allow contemporaneous investors to buy or sell Shares at approximately the same intraday price.

22. The relief from section 22(d) and rule 22c-1 requested by applicants is significantly different from the relief previously granted by the Commission to actively managed ETFs. ETFs require relief from these provisions because certain investors may purchase and sell individual ETF shares on the secondary market at current market prices; *i.e.*, at prices other than those described in the ETF's prospectus or based on the ETF's NAV. Among other things, the market prices are affected by changes in the value of the underlying portfolio positions of the ETF.

23. Historically, in making the findings necessary to grant exemptive relief from section 22(d) and rule 22c-1, the Commission has relied on representations by ETF sponsors that an arbitrage mechanism functions to keep the market price of the ETF's shares at or close to the NAV per share of the ETF. The close tie between the market price and the NAV per share of the ETF is the foundation for why the prices at which retail investors buy and sell shares are similar to the prices at which Authorized Participants are able to buy and redeem shares directly from the ETF at NAV.

24. ETMF trading prices, as discussed above, would be directly tied to NAV. Unlike ETFs, ETMFs' need for relief arises because their trading price deviate from NAV only with respect to the execution costs of buying and selling ETMF Shares (*i.e.*, the premium/discount). In contrast, ETFs need relief because of differences related to the value of the underlying portfolio positions. Therefore, because ETMF Shares' trading prices are directly tied to NAV, an arbitrage mechanism that would keep market price close to or at NAV is not necessary.

25. Accordingly, the Commission preliminarily agrees that any amount of premium or discount will be limited in the manner explained by applicants and that the concerns underlying section 22(d) and rule 22c-1 thereunder are addressed by the NAV-based Trading of

Shares proposed by the applicants. Any differences from the ETMF proposed model, however, would not necessarily address those concerns.

*B. Other Relief*²³

Sections 5(a)(1) and 2(a)(32) of the Act

26. Section 5(a)(1) of the Act defines an "open-end company" as a management investment company that is offering for sale or has outstanding any redeemable security of which it is the issuer. Section 2(a)(32) of the Act defines a redeemable security as any security, other than short-term paper, under the terms of which the holder, upon its presentation to the issuer, is entitled to receive approximately a proportionate share of the issuer's current net assets, or the cash equivalent. Because Shares would not be individually redeemable, applicants request an order that would permit the Trusts to register as open-end investment companies and each ETMF to redeem Shares in Creation Units only.²⁴ Applicants state that investors may purchase Shares in Creation Units from each ETMF and redeem Creation Units from each ETMF. Applicants further state all investors would have the ability to buy and sell Shares throughout the day using NAV-based Trading at trading prices that are directly linked to NAV and that can be expected to reflect narrow premium/discounts to NAV.

Section 22(e) of the Act

27. Section 22(e) of the Act generally prohibits a registered investment company from suspending the right of redemption or postponing the date of payment of redemption proceeds for more than seven days after the tender of a security for redemption. Applicants observe that settlement of redemptions of Creation Units of ETMFs holding Portfolio Positions traded on global markets ("Global ETMFs") is contingent not only on the settlement cycle of the U.S. securities markets but also on the delivery cycles present in foreign markets in which those ETMFs invest. Applicants represent that, under certain circumstances, the delivery cycles for transferring foreign-traded Basket Instruments to redeeming investors, coupled with local market holiday schedules, would require a delivery process of up to 14 calendar days. Applicants therefore request relief from

section 22(e) in order to provide payment or satisfaction of redemptions within the maximum number of calendar days required for such payment or satisfaction in the principal local markets where transactions in the foreign-traded Basket Instruments of each Global ETMF customarily clear and settle, but in all cases no later than 14 calendar days following the tender of a Creation Unit.²⁵

28. Applicants state that section 22(e) was designed to prevent unreasonable, undisclosed and unforeseen delays in the actual payment of redemption proceeds. Applicants state that allowing redemption payments in kind for Creation Units of a Global ETMF to be made within a maximum of 14 calendar days would not be inconsistent with the spirit and intent of section 22(e). Applicants state each ETMF's statement of additional information ("SAI") would disclose those local holidays (over the period of at least one year following the date of the SAI), if any, that are expected to prevent the delivery of redemption proceeds in kind in seven calendar days and the maximum number of days (not to exceed 14 calendar days) needed to deliver the proceeds in kind for each affected ETMF. Applicants are not seeking relief from section 22(e) with respect to Global ETMFs that do not effect redemptions in kind.

Section 12(d)(1) of the Act

29. Section 12(d)(1)(A) of the Act prohibits a registered investment company from acquiring shares of an investment company if the securities represent more than 3% of the total outstanding voting stock of the acquired company, more than 5% of the total assets of the acquiring company, or, together with the securities of any other investment companies, more than 10% of the total assets of the acquiring company. Section 12(d)(1)(B) of the Act prohibits a registered open-end investment company, its principal underwriter, or any other broker or dealer from selling its shares to another investment company if the sale will cause the acquiring company to own more than 3% of the acquired company's voting stock, or if the sale

²⁵ Applicants acknowledge that no relief obtained from the requirements of section 22(e) would affect any obligations that applicants may otherwise have under rule 15c6-1 under the Exchange Act. Rule 15c6-1 requires that most securities transactions be settled within three business days of the trade date. Mutual Fund Feeders (as defined below) may need to separately seek relief from section 22(e) if they intend to permit or require their shareholders to redeem in kind. Mutual Fund Feeders are not seeking, and would not rely on, the section 22(e) relief requested herein.

²³ This other relief is the same relief that the Commission has previously granted to permit the operation of ETFs, as stated above.

²⁴ The Master Funds will not require relief from sections 2(a)(32) and 5(a)(1) because the Master Funds will operate as traditional mutual funds and issue individually redeemable interests.

will cause more than 10% of the acquired company's voting stock to be owned by investment companies generally.

30. Applicants are seeking relief so that an ETMF may be an acquired fund in a fund of funds structure. In particular, applicants request that pursuant to section 12(d)(1)(J) of the Act the order permit Acquiring Funds (as defined below) to acquire Shares of an ETMF beyond the limitations in section 12(d)(1)(A) and permit an ETMF, any principal underwriter for the ETMFs,²⁶ and any Brokers (as defined below) to sell Shares to Acquiring Funds beyond the limitations in section 12(d)(1)(B) ("Section 12(d)(1) Relief"). Applicants request that the Section 12(d)(1) Relief apply to each management investment company or unit investment trust registered under the Act that is not part of the same "group of investment companies" as an ETMF within the meaning of section 12(d)(1)(G)(ii) of the Act and that enters into an Acquiring Fund Agreement (as defined below) with an ETMF (such management investment companies, "Acquiring Management Companies," such unit investment trusts, "Acquiring Trusts," and Acquiring Management Companies and Acquiring Trusts together, "Acquiring Funds").²⁷ Acquiring Funds do not include the ETMFs.²⁸ Applicants submit that the proposed conditions to the requested relief address the limits in section 12(d)(1), which include concerns about undue influence, excessive layering of fees and overly complex structures.

31. Applicants submit that their proposed conditions address any concerns regarding the potential for undue influence. To limit the control that an Acquiring Fund may have over an ETMF, applicants propose a condition prohibiting the adviser of an Investing Management Company ("Acquiring Fund Adviser"), sponsor of an Acquiring Trust ("Sponsor"), any

person controlling, controlled by, or under common control with the Acquiring Fund Adviser or Sponsor, and any investment company or issuer that would be an investment company but for sections 3(c)(1) or 3(c)(7) of the Act that is advised or sponsored by the Acquiring Fund Adviser, the Sponsor, or any person controlling, controlled by, or under common control with the Acquiring Fund Adviser or Sponsor ("Acquiring Fund's Advisory Group") from controlling (individually or in the aggregate) an ETMF within the meaning of section 2(a)(9) of the Act. The same prohibition would apply to any sub-adviser to an Acquiring Management Company ("Acquiring Fund Sub-Adviser"), any person controlling, controlled by or under common control with the Acquiring Fund Sub-Adviser, and any investment company or issuer that would be an investment company but for sections 3(c)(1) or 3(c)(7) of the Act (or portion of such investment company or issuer) advised or sponsored by the Acquiring Fund Sub-Adviser or any person controlling, controlled by or under common control with the Acquiring Fund Sub-Adviser ("Acquiring Fund's Sub-Advisory Group").

32. To limit undue influence, applicants propose a condition to ensure that no Acquiring Fund or Acquiring Fund Affiliate²⁹ (except to the extent it is acting in its capacity as an investment adviser to an ETMF) will cause an ETMF (or, in the case of an ETMF Feeder, its Master Fund) to purchase a security in an offering of securities during the existence of an underwriting or selling syndicate of which a principal underwriter is an Underwriting Affiliate ("Affiliated Underwriting"). An "Underwriting Affiliate" is a principal underwriter in any underwriting or selling syndicate that is an officer, director, member of an advisory board, Acquiring Fund Adviser, Acquiring Fund Sub-Adviser, Sponsor, or employee of the Acquiring Fund, or a person of which any such officer, director, member of an advisory board, Acquiring Fund Adviser, Acquiring Fund Sub-Adviser, Sponsor, or employee is an affiliated person (except any person whose relationship to the ETMF is covered by section 10(f)

of the Act is not an Underwriting Affiliate).

33. Applicants propose several conditions to address the potential for layering of fees. Applicants note that the board of directors or trustees of any Acquiring Management Company, including a majority of the directors or trustees who are not "interested persons" within the meaning of section 2(a)(19) of the Act ("disinterested directors or trustees"), would be required to find that the advisory fees charged under the Acquiring Management Company's advisory contract are based on services provided that would be in addition to, rather than duplicative of, services provided under the advisory contract of any ETMF (or, in the case of an ETMF Feeder, its Master Fund) in which the Acquiring Management Company may invest. Applicants also state that any sales charges and/or service fees charged with respect to shares of an Acquiring Fund will not exceed the limits applicable to a fund of funds as set forth in NASD Conduct Rule 2830.

34. Applicants submit that the proposed arrangement would not create an overly complex fund structure. Applicants note that an ETMF (and, in the case of an ETMF Feeder, the Master Fund) would be prohibited from acquiring securities of any investment company or company relying on section 3(c)(1) or 3(c)(7) of the Act in excess of the limits contained in section 12(d)(1)(A) of the Act, except to the extent that the ETMF acquires such securities in compliance with section 12(d)(1)(E) of the Act or this order or the ETMF (or, in the case of an ETMF Feeder, the Master Fund): (a) Receives securities of another investment company as a dividend or as a result of a plan of reorganization of a company (other than a plan devised for the purpose of evading section 12(d)(1) of the Act); or (b) acquires (or is deemed to have acquired) securities of another investment company pursuant to exemptive relief from the Commission permitting the ETMF (or in the case of a ETMF Feeder, the Master Fund) to (i) acquire securities of one or more investment companies for short-term cash management purposes or (ii) engage in interfund borrowing and lending transactions.

35. To ensure that an Acquiring Fund is aware of the terms and conditions of the requested order, the Acquiring Fund must enter into an agreement with the respective ETMFs ("Acquiring Fund Agreement"). The Acquiring Fund Agreement will include an acknowledgement from the Acquiring Fund that it may rely on the order only

²⁶ Applicants further request that the order apply to any future distributor and principal underwriter of the ETMFs (included in the term "Distributor"), which would be a registered broker-dealer under the Exchange Act (any registered broker-dealers, "Brokers") and would comply with the terms and conditions of the requested order. The Distributor of any ETMF may be an affiliated person of the Adviser.

²⁷ Under condition 11, the Section 12(d)(1) Relief would generally not apply to any ETMF that is, either directly or through a master-feeder structure, acquiring securities of any investment company or company relying on section 3(c)(1) or 3(c)(7) of the Act in excess of the limits in section 12(d)(1)(A) of the Act.

²⁸ An Acquiring Fund may rely on the order only to invest in ETMFs and not in any other registered investment companies.

²⁹ An "Acquiring Fund Affiliate" is any Acquiring Fund Adviser, Acquiring Fund Sub-Adviser, Sponsor, promoter and principal underwriter of an Acquiring Fund, and any person controlling, controlled by or under common control with any of these entities. "ETMF Affiliate" is an investment adviser, promoter, or principal underwriter of an ETMF (or, in the case of an ETMF Feeder, its Master Fund) and any person controlling, controlled by or under common control with any of these entities.

to invest in an ETMF and not in any other investment company.

36. Applicants further request relief to permit an ETMF to be a feeder (an “ETMF Feeder”) in a master-feeder structure alongside one or more other registered open-end investment companies advised by the same Adviser (each such other open-end investment company, a “Mutual Fund Feeder,” and together with any ETMF Feeder, the “Feeder Funds”). The requested relief would permit the ETMF Feeder to acquire shares of another registered investment company in the same group of investment companies having substantially the same investment objectives as the ETMF Feeder (a “Master Fund”) beyond the limitations in section 12(d)(1)(A) of the Act and permit the Master Fund, and any principal underwriter for the Master Fund, to sell shares of the Master Fund to the ETMF Feeder beyond the limitations in section 12(d)(1)(B) of the Act (“Master-Feeder Relief”).³⁰ There would be no ability by shareholders to exchange Shares of ETMF Feeders for shares of another Feeder Fund of the Master Fund or vice versa.

37. Applicants are seeking the Master-Feeder Relief to permit ETMF Feeders to create and redeem in kind Shares with their Master Funds. Applicants assert that this structure is substantially identical to traditional master-feeder structures permitted pursuant to the exception provided in section 12(d)(1)(E) of the Act. Section 12(d)(1)(E) provides that the percentage limitations of sections 12(d)(1)(A) and (B) will not apply to a security issued by an investment company (in this case, the shares of the applicable Master Fund) if, among other things, that security is the only investment security held in the investing fund’s portfolio (in this case, the ETMF Feeder’s portfolio). Applicants believe the proposed master-feeder structure complies with section 12(d)(1)(E) because each ETMF Feeder would hold only investment securities issued by its corresponding Master Fund; however, the ETMF Feeders may receive securities other than securities of its corresponding Master Fund if an ETMF Feeder accepts an in-kind

creation. To the extent that an ETMF Feeder may be deemed to be holding both shares of the Master Fund and other securities, applicants request relief from sections 12(d)(1)(A) and (B). The ETMF Feeders would operate in compliance with all other provisions of section 12(d)(1)(E).

Sections 17(a)(1) and (2) of the Act

38. Section 17(a) of the Act generally prohibits an affiliated person of a registered investment company, or an affiliated person of such a person (“second-tier affiliate”), from selling any security to or purchasing any security from the company. Section 2(a)(3) of the Act defines “affiliated person” to include any person directly or indirectly owning, controlling, or holding with power to vote, 5% or more of the outstanding voting securities of the other person and any person directly or indirectly controlling, controlled by, or under common control with, the other person. Section 2(a)(9) of the Act defines “control” as the power to exercise a controlling influence over the management or policies of a company and provides that a control relationship will be presumed where one person owns more than 25% of another person’s voting securities. Each ETMF may be deemed to be controlled by an Adviser and hence affiliated persons of each other. In addition, the ETMFs may be deemed to be under common control with any other registered investment company (or series thereof) advised by an Adviser (an “Affiliated Fund”).

39. Applicants request an exemption under sections 6(c) and 17(b) of the Act from sections 17(a)(1) and 17(a)(2) of the Act to permit in-kind purchases and redemptions of Creation Units by persons that are affiliated persons or second-tier affiliates of the ETMFs solely by virtue of one or more of the following: (a) Holding 5% or more, or in excess of 25% of the outstanding Shares of one or more ETMFs; (b) having an affiliation with a person with an ownership interest described in (a); or (c) holding 5% or more, or more than 25% of the Shares of one or more Affiliated Funds.³¹ Applicants also request an exemption in order to permit an ETMF to sell its Shares to and redeem its Shares from, and engage in the in-kind transactions that would accompany such sales and redemptions with, an Acquiring Fund of which the

ETMF is an affiliated person or a second-tier affiliate.³²

40. Applicants assert that no useful purpose would be served by prohibiting such affiliated persons from making in-kind purchases or in-kind redemptions of Shares of an ETMF in Creation Units. Absent the limited circumstances discussed in the application, the Basket Instruments available for an ETMF would be the same for all purchasers and redeemers, respectively. The deposit procedures for in-kind purchases of Creation Units and the redemption procedures for in-kind redemptions would be the same for all purchases and redemptions. All Basket Instruments would be valued in the same manner as they are valued for purposes of calculating the ETMF’s NAV, and such valuation would be made in the same manner regardless of the identity of the purchaser or redeemer. Applicants do not believe that in-kind purchases and redemptions would result in abusive self-dealing or overreaching of the ETMF.

41. Applicants also submit that the sale of Shares to and redemption of Shares from an Acquiring Fund meets the standards for relief under sections 17(b) and 6(c) of the Act. Applicants note that any consideration paid for the purchase or redemption of Shares directly from an ETMF would be based on the NAV of the ETMF in accordance with policies and procedures set forth in the ETMF’s registration statement.³³ The Acquiring Fund Agreement will require any Acquiring Fund that purchases Creation Units directly from an ETMF to represent that the purchase of Creation Units from an ETMF by an Acquiring Fund will be accomplished in compliance with the investment restrictions of the Acquiring Fund and will be consistent with the investment policies set forth in the Acquiring Fund’s registration statement. Applicants also state that the proposed transactions are consistent with the general purposes of the Act and appropriate in the public interest.

42. To the extent that an ETMF operates in a master-feeder structure,

³² To the extent that purchases and sales of Shares occur in the secondary market and not through principal transactions directly between an Acquiring Fund and an ETMF, relief from section 17(a) would not be necessary. The requested relief is intended to cover, however, transactions directly between an Acquiring Fund and an ETMF.

³³ Applicants acknowledge that the receipt of compensation by (a) an affiliated person of an Acquiring Fund, or a second-tier affiliate, for the purchase by the Acquiring Fund of Shares of the ETMF or (b) an affiliated person of an ETMF, or a second-tier affiliate, for the sale by the ETMF of its Shares to an Acquiring ETMF, may be prohibited by section 17(e)(1) of the Act. The Acquiring Fund Agreement also will include this acknowledgment.

³⁰ Applicants may structure certain ETMFs as ETMF Feeders to generate economies of scale for shareholders of all Feeder Funds of the Master Fund that could not be otherwise realized. Operating in a master-feeder structure could also impose costs on an ETMF Feeder and reduce its tax efficiency. In determining whether an ETMF would operate in a master-feeder structure, the Board would weigh the potential advantages and disadvantages of such a structure for the ETMF. In a master-feeder structure, the Master Fund—rather than the ETMF Feeder—would invest the portfolio in compliance with the order.

³¹ Applicants are not seeking relief from section 17(a) for, and the requested relief will not apply to, transactions where an ETMF could be deemed an affiliated person, or an affiliated person of an affiliated person, of an Acquiring Fund because the Adviser to the ETMF is also an investment adviser to an Acquiring Fund.

applicants also request relief permitting the ETMF Feeders to engage in in-kind creations and redemptions with the applicable Master Fund. Applicants state that the customary section 17(a)(1) and 17(a)(2) relief would not be sufficient to permit such transactions because the ETMF Feeders and the applicable Master Fund could also be affiliated by virtue of having the same investment adviser.

However, applicants believe that in-kind creations and redemptions between an ETMF Feeder and a Master Fund advised by the same investment adviser do not involve "overreaching" by an affiliated person. Such transactions would occur only at the ETMF Feeder's proportionate share of the Master Fund's net assets, and the Basket Instruments would be valued in the same manner as they are valued for the purposes of calculating the applicable Master Fund's NAV. Further, all such transactions would be effected with respect to the Basket and on the same terms with respect to all investors. Finally, such transactions would only occur as a result of, and to effectuate, a creation or redemption transaction between the ETMF Feeder and a third party investor. Applicants believe that the terms of the proposed transactions are reasonable and fair and do not involve overreaching on the part of any person concerned and that the transactions are consistent with the general purposes of the Act.

Applicants' Conditions

Applicants agree that any order of the Commission granting the requested relief will be subject to the following conditions:

A. ETMF Relief

1. As long as an ETMF operates in reliance on the requested order, its Shares will be listed on an Exchange.

2. Neither the Trusts nor any ETMF will be advertised or marketed as an open-end investment company, a mutual fund or an ETF. Any advertising material that describes the purchase or sale of Creation Units or refers to redeemability will prominently disclose that Shares are not individually redeemable and that owners of Shares may acquire those Shares from an ETMF and tender those Shares for redemption to the ETMF in Creation Units only.

3. The Web site for the ETMFs, which will be publicly accessible at no charge, will contain, on a per Share basis, for each ETMF, the prior Business Day's NAV; intraday high, low, average and closing trading prices (expressed as premiums/discounts to NAV); the midpoint of the highest bid and lowest

offer prices as of the close of Exchange trading ("Closing Bid/Ask Midpoint") (expressed as a premium/discount to NAV); and the spread between the highest bid and lowest offer prices as of the close of Exchange trading ("Closing Bid/Ask Spread"). The Web site for the ETMFs also will contain charts showing the frequency distribution and range of values of trading prices, Closing Bid/Ask Midpoints and Closing Bid/Ask Spreads over time.

4. The Adviser or any Subadviser, directly or indirectly, will not cause any Authorized Participant (or any investor on whose behalf an Authorized Participant may transact with the ETMF) to acquire any Basket Instrument for the ETMF through a transaction in which the ETMF could not engage directly.

B. Section 12(d)(1) Relief

1. The members of an Acquiring Fund's Advisory Group will not control (individually or in the aggregate) an ETMF (or, in the case of an ETMF Feeder, its Master Fund) within the meaning of section 2(a)(9) of the Act. The members of an Acquiring Fund's Subadvisory Group will not control (individually or in the aggregate) an ETMF (or, in the case of an ETMF Feeder, its Master Fund) within the meaning of section 2(a)(9) of the Act. If, as a result of a decrease in the outstanding voting securities of the ETMF, the Acquiring Fund's Advisory Group or the Acquiring Fund's Subadvisory Group, each in the aggregate, becomes a holder of more than 25 percent of the outstanding voting securities of an ETMF, it will vote its Shares of the ETMF in the same proportion as the vote of all other holders of such Shares. This condition does not apply to the Acquiring Fund's Subadvisory Group with respect to an ETMF (or, in the case of an ETMF Feeder, its Master Fund) for which the Acquiring Fund Subadviser or a person controlling, controlled by or under common control with the Acquiring Fund Subadviser acts as the investment adviser within the meaning of section 2(a)(20)(A) of the Act.

2. No Acquiring Fund or Acquiring Fund Affiliate will cause any existing or potential investment by the Acquiring Fund in an ETMF to influence the terms of any services or transactions between the Acquiring Fund or an Acquiring Fund Affiliate and the ETMF (or, in the case of an ETMF Feeder, its Master Fund) or an ETMF Affiliate.

3. The board of directors or trustees of an Acquiring Management Company, including a majority of the disinterested directors or trustees, will adopt

procedures reasonably designed to ensure that the Acquiring Fund Adviser and any Acquiring Fund Subadviser are conducting the investment program of the Acquiring Management Company without taking into account any consideration received by the Acquiring Management Company or an Acquiring Fund Affiliate from an ETMF (or, in the case of an ETMF Feeder, its Master Fund) or an ETMF Affiliate in connection with any services or transactions.

4. Once an investment by an Acquiring Fund in the Shares of an ETMF exceeds the limit in section 12(d)(1)(A)(i) of the Act, the Board of the ETMF, including a majority of the disinterested directors or trustees, will determine that any consideration paid by the ETMF (or, in the case of an ETMF Feeder, its Master Fund) to an Acquiring Fund or an Acquiring Fund Affiliate in connection with any services or transactions: (i) Is fair and reasonable in relation to the nature and quality of the services and benefits received by the ETMF (or, in the case of an ETMF Feeder, its Master Fund); (ii) is within the range of consideration that the ETMF (or, in the case of an ETMF Feeder, its Master Fund) would be required to pay to another unaffiliated entity in connection with the same services or transactions; and (iii) does not involve overreaching on the part of any person concerned. This condition does not apply to any services or transactions between an ETMF (or, in the case of an ETMF Feeder, its Master Fund) and its investment adviser(s), or any person controlling, controlled by or under common control with such investment adviser(s).

5. No Acquiring Fund or Acquiring Fund Affiliate (except to the extent it is acting in its capacity as an investment adviser to an ETMF (or, in the case of an ETMF Feeder, its Master Fund)) will cause an ETMF (or, in the case of an ETMF Feeder, its Master Fund) to purchase a security in an Affiliated Underwriting.

6. The Board of an ETMF (or, in the case of an ETMF Feeder, its Master Fund), including a majority of the disinterested directors or trustees, will adopt procedures reasonably designed to monitor any purchases of securities by the ETMF (or, in the case of an ETMF Feeder, its Master Fund) in an Affiliated Underwriting, once an investment by an Acquiring Fund in the securities of the ETMF exceeds the limit of section 12(d)(1)(A)(i) of the Act, including any purchases made directly from an Underwriting Affiliate. The Board will review these purchases periodically, but no less frequently than annually, to

determine whether the purchases were influenced by the investment by the Acquiring Fund in the ETMF. The Board will consider, among other things: (i) Whether the purchases were consistent with the investment objectives and policies of the ETMF (or, in the case of an ETMF Feeder, its Master Fund); (ii) how the performance of securities purchased in an Affiliated Underwriting compares to the performance of comparable securities purchased during a comparable period of time in underwritings other than Affiliated Underwritings or to a benchmark such as a comparable market index; and (iii) whether the amount of securities purchased by the ETMF (or, in the case of an ETMF Feeder, its Master Fund) in Affiliated Underwritings and the amount purchased directly from an Underwriting Affiliate have changed significantly from prior years. The Board will take any appropriate actions based on its review, including, if appropriate, the institution of procedures designed to assure that purchases of securities in Affiliated Underwritings are in the best interest of shareholders of the ETMF.

7. Each ETMF (or, in the case of an ETMF Feeder, its Master Fund) will maintain and preserve permanently in an easily accessible place a written copy of the procedures described in the preceding condition, and any modifications to such procedures, and will maintain and preserve for a period of not less than six years from the end of the fiscal year in which any purchase in an Affiliated Underwriting occurred, the first two years in an easily accessible place, a written record of each purchase of securities in Affiliated Underwritings, once an investment by an Acquiring Fund in the securities of the ETMF exceeds the limit of section 12(d)(1)(A)(i) of the Act, setting forth from whom the securities were acquired, the identity of the underwriting syndicate's members, the terms of the purchase, and the information or materials upon which the determinations of the Board were made.

8. Before investing in an ETMF in excess of the limits in section 12(d)(1)(A), an Acquiring Fund and the ETMF will execute an Acquiring Fund Agreement stating that their boards of directors or trustees and their investment advisers, or Trustee and Sponsor, as applicable, understand the terms and conditions of the order, and agree to fulfill their responsibilities under the order. At the time of its investment in Shares of an ETMF in excess of the limit in section

12(d)(1)(A)(i), an Acquiring Fund will notify the ETMF of the investment. At such time, the Acquiring Fund will also transmit to the ETMF a list of the names of each Acquiring Fund Affiliate and Underwriting Affiliate. The Acquiring Fund will notify the ETMF of any changes to the list of the names as soon as reasonably practicable after a change occurs. The ETMF and the Acquiring Fund will maintain and preserve a copy of the order, the Acquiring Fund Agreement, and the list with any updated information for the duration of the investment and for a period of not less than six years thereafter, the first two years in an easily accessible place.

9. The Acquiring Fund Adviser, or Trustee or Sponsor, as applicable, will waive fees otherwise payable to it by the Acquiring Fund in an amount at least equal to any compensation received from an ETMF (or, in the case of an ETMF Feeder, its Master Fund) by the Acquiring Fund Adviser, or Trustee, or Sponsor, or an affiliated person of the Acquiring Fund Adviser, or Trustee, or Sponsor, other than any advisory fees paid to the Acquiring Fund Adviser, or Trustee, or Sponsor, or its affiliated person by the ETMF (or, in the case of an ETMF Feeder, its Master Fund), in connection with the investment by the Acquiring Fund in the ETMF. Any Acquiring Fund Subadviser will waive fees otherwise payable to the Acquiring Fund Subadviser, directly or indirectly, by the Acquiring Management Company in an amount at least equal to any compensation received from an ETMF (or, in the case of an ETMF Feeder, its Master Fund) by the Acquiring Fund Subadviser, or an affiliated person of the Acquiring Fund Subadviser, other than any advisory fees paid to the Acquiring Fund Subadviser or its affiliated person by the ETMF (or, in the case of an ETMF Feeder, its Master Fund), in connection with any investment by the Acquiring Management Company in the ETMF made at the direction of the Acquiring Fund Subadviser. In the event that the Acquiring Fund Subadviser waives fees, the benefit of the waiver will be passed through to the Acquiring Management Company.

10. Any sales charges and/or service fees charged with respect to shares of an Acquiring Fund will not exceed the limits applicable to a fund of funds as set forth in NASD Conduct Rule 2830.

11. No ETMF (or, in the case of an ETMF Feeder, its Master Fund) relying on the Section 12(d)(1) relief will acquire securities of any investment company or company relying on section 3(c)(1) or 3(c)(7) of the Act in excess of the limits contained in section 12(d)(1)(A) of the Act, except to the

extent that the ETMF acquires such securities in compliance with section 12(d)(1)(E) of the Act or acquires shares of a Master Fund; or the ETMF (or, in the case of an ETMF Feeder, its Master Fund) (a) Receives securities of another investment company as a dividend or as a result of a plan of reorganization of a company (other than a plan devised for the purpose of evading section 12(d)(1) of the Act), or (b) acquires securities of another investment company pursuant to exemptive relief from the Commission permitting such ETMF (or, in the case of an ETMF Feeder, its Master Fund) to (i) Acquire securities of one or more investment companies for short-term cash management purposes or (ii) engage in interfund borrowing and lending transactions.

12. Before approving any advisory contract under section 15 of the Act, the board of each Acquiring Management Company, including a majority of the disinterested directors or trustees, will find that the advisory fees charged under such advisory contract are based on services provided that will be in addition to, rather than duplicative of, the services provided under the advisory contracts of any ETMF (or, in the case of an ETMF Feeder, its Master Fund) in which the Acquiring Management Company may invest. These findings and their basis will be recorded fully in the minute books of the appropriate Acquiring Management Company.

By the Commission.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014-26817 Filed 11-12-14; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 31332; 812-14236]

AllianceBernstein Cap Fund, Inc., et al.; Notice of Application

November 6, 2014.

AGENCY: Securities and Exchange Commission ("Commission").

ACTION: Notice of an application for an order under section 12(d)(1)(j) of the Investment Company Act of 1940 (the "Act") for exemptions from sections 12(d)(1)(A), (B), and (C) of the Act, under sections 6(c) and 17(b) of the Act for an exemption from section 17(a) of the Act, and under section 6(c) of the Act for an exemption from rule 12d1-2(a) under the Act.

SUMMARY OF THE APPLICATION:

Applicants request an order that would (a) permit certain registered open-end management investment companies that operate as “funds of funds” to acquire shares of certain registered open-end management investment companies, registered closed-end management investment companies, business development companies as defined by section 2(a)(48) of the Act (“business development companies”), and registered unit investment trusts that are within or outside the same group of investment companies as the acquiring investment companies and (b) permit certain registered open-end management investment companies relying on rule 12d1–2 under the Act to invest in certain financial instruments.

APPLICANTS: AllianceBernstein Cap Fund, Inc. (the “Company”), AllianceBernstein L.P. (the “Adviser”), and AllianceBernstein Investments, Inc. (the “Distributor”).

DATES: *Filing Dates:* The application was filed on November 14, 2013, and amended on June 10, 2014, August 22, 2014, and November 4, 2014.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission’s Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on December 1, 2014, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer’s interest, any facts bearing on the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission’s Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicants: c/o Emilie D. Wrapp, 1345 Avenue of the Americas, New York, NY 10105.

FOR FURTHER INFORMATION CONTACT:

Deepak T. Pai, Senior Counsel, at (202) 551–6876, or Mary Kay Frech, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel’s Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission’s

Web site by searching for the file number, or for an applicant using the “Company” name box, at <http://www.sec.gov/search/search.htm> or by calling (202) 551–8090.

Applicants’ Representations

1. The Company is an open-end management investment company registered under the Act and organized as a Maryland corporation. The Company has multiple series, which pursue distinct investment objectives and strategies. Applicants request that the order apply not only to any existing series of the Company, but also to any future series of the Company, and any other existing or future registered open-end management investment companies and any series thereof that are part of the same group of investment companies, as defined in section 12(d)(1)(G)(ii) of the Act, as the Company and are, or may in the future be, advised by the Adviser or any other investment adviser controlling, controlled by, or under common control with the Adviser (together with the existing series of the Company, each series a “Fund,” and collectively, the “Funds”).¹

2. The Adviser, a Delaware limited partnership, is registered as an investment adviser under the Investment Advisers Act of 1940 (the “Advisers Act”), and serves as the investment adviser to the existing Funds.² The Distributor is a Broker (as defined below) and serves as the existing Funds’ principal underwriter and distributor.

3. Applicants request relief to the extent necessary to permit: (a) A Fund (each, a “Fund of Funds,” and collectively, the “Funds of Funds”) to acquire shares of registered open-end management investment companies (each, an “Unaffiliated Open-End Investment Company”), registered closed-end management investment companies, business development companies (each registered closed-end management investment company and each business development company, an “Unaffiliated Closed-End Investment Company” and, together with the Unaffiliated Open-End Investment Companies, the “Unaffiliated Investment Companies”), and registered unit investment trusts (“UITs”) (the

“Unaffiliated Trusts,” and together with the Unaffiliated Investment Companies, the “Unaffiliated Funds”), in each case, that are not part of the same “group of investment companies” as the Funds of Funds;³ (b) the Unaffiliated Open-End Investment Companies, their principal underwriters and any broker or dealer registered under the Securities Exchange Act of 1934 (the “1934 Act”) (“Broker”) to sell shares of such Unaffiliated Open-End Investment Companies to the Funds of Funds; (c) the Funds of Funds to acquire shares of other registered investment companies, including open-end management investment companies and series thereof, closed-end management investment companies and UITs, as well as business development companies, in the same group of investment companies as the Funds of Funds (collectively, the “Affiliated Funds,” and, together with the Unaffiliated Funds, the “Underlying Funds”);⁴ and (d) the Affiliated Funds that are registered open-end management investment companies, their principal underwriters and any Broker to sell shares of the Affiliated Funds to the Funds of Funds. Applicants also request an order under sections 6(c) and 17(b) of the Act to exempt applicants from section 17(a) to the extent necessary to permit certain Underlying Funds to sell their shares to Funds of Funds and redeem their shares from Funds of Funds.

4. Applicants also request an exemption under section 6(c) from rule 12d1–2 under the Act to permit any existing or future Fund that relies on

³ For purposes of the request for relief from sections 12(d)(1)(A), (B), and (C) of the Act, the term “group of investment companies” means any two or more registered investment companies (including closed-end investment companies) or business development companies that hold themselves out to investors as related companies for purposes of investment and investor services.

⁴ Certain of the Underlying Funds may be registered under the Act as either UITs or open-end management investment companies and have obtained exemptions from the Commission necessary to permit their shares to be listed and traded on a national securities exchange at negotiated prices and, accordingly, to operate as exchange-traded funds (collectively, “ETFs” and each, an “ETF”). In addition, certain of the Underlying Funds may now or in the future pursue their investment objectives through a master-feeder arrangement in reliance on section 12(d)(1)(E) of the Act. In accordance with condition 12, a Fund of Funds may not invest in an Underlying Fund that operates as a feeder fund unless the feeder fund is part of the same “group of investment companies” as its corresponding master fund or the Fund of Funds. If a Fund of Funds invests in an Affiliated Fund that operates as a feeder fund and the corresponding master fund is not within the same “group of investment companies” as the Fund of Funds and Affiliated Fund, the master fund would be an Unaffiliated Fund for purposes of the application and its conditions.

¹ All entities that currently intend to rely on the requested order are named as applicants. Any other entity that relies on the order in the future will comply with the terms and conditions of the application.

² All references to the term “Adviser” include any successors in interest to the Adviser. A successor is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization.

section 12(d)(1)(G) of the Act (“Section 12(d)(1)(G) Fund”) and that otherwise complies with rule 12d1–2 under the Act, to also invest, to the extent consistent with its investment objective(s), policies, strategies and limitations, in other financial instruments that may not be securities within the meaning of section 2(a)(36) of the Act (“Other Investments”).

Applicants’ Legal Analysis

A. Section 12(d)(1)

1. Section 12(d)(1)(A) of the Act, in relevant part, prohibits a registered investment company from acquiring shares of an investment company if the securities represent more than 3% of the total outstanding voting stock of the acquired company, more than 5% of the total assets of the acquiring company, or, together with the securities of any other investment companies, more than 10% of the total assets of the acquiring company. Section 12(d)(1)(B) of the Act prohibits a registered open-end investment company, its principal underwriter, and any broker or dealer from selling the investment company’s shares to another investment company if the sale will cause the acquiring company to own more than 3% of the acquired company’s voting stock, or if the sale will cause more than 10% of the acquired company’s voting stock to be owned by investment companies generally. Section 12(d)(1)(C) prohibits an investment company from acquiring any security issued by a registered closed-end investment company if such acquisition would result in the acquiring company, any other investment companies having the same investment adviser, and companies controlled by such investment companies, collectively, owning more than 10% of the outstanding voting stock of the registered closed-end investment company.

2. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors. Applicants request an exemption under section 12(d)(1)(J) of the Act from the limitations of sections 12(d)(1)(A), (B) and (C) of the Act to the extent necessary to permit: (i) The Funds of Funds to acquire shares of Underlying Funds in excess of the limits set forth in section 12(d)(1)(A) and (C) of the Act; and (ii) the Underlying Funds that are registered open-end management investment companies, their principal

underwriters and any Broker to sell shares of the Underlying Funds to the Funds of Funds in excess of the limits set forth in section 12(d)(1)(B) of the Act.

3. Applicants state that the proposed arrangement will not give rise to the policy concerns underlying sections 12(d)(1)(A), (B), and (C), which include concerns about undue influence by a fund of funds over underlying funds, excessive layering of fees, and overly complex fund structures. Accordingly, applicants believe that the requested exemption is consistent with the public interest and the protection of investors.

4. Applicants submit that the proposed structure will not result in the exercise of undue influence by a Fund of Funds or its affiliated persons over the Underlying Funds. Applicants assert that the concern about undue influence does not arise in connection with a Fund of Funds’ investment in the Affiliated Funds because they are part of the same group of investment companies. To limit the control a Fund of Funds or Fund of Funds Affiliate⁵ may have over an Unaffiliated Fund, applicants propose a condition prohibiting the Adviser and any person controlling, controlled by or under common control with the Adviser, and any investment company and any issuer that would be an investment company but for section 3(c)(1) or section 3(c)(7) of the Act advised or sponsored by the Adviser or any person controlling, controlled by or under common control with the Adviser (collectively, the “Group”) from controlling (individually or in the aggregate) an Unaffiliated Fund within the meaning of section 2(a)(9) of the Act. The same prohibition would apply to any other investment adviser within the meaning of section 2(a)(20)(B) of the Act (“Sub-Adviser”) and any person controlling, controlled by or under common control with the Sub-Adviser, and any investment company or issuer that would be an investment company but for section 3(c)(1) or 3(c)(7) of the Act (or portion of such investment company or issuer) advised or sponsored by the Sub-Adviser or any person controlling, controlled by or under common control with the Sub-Adviser (collectively, the “Sub-Adviser Group”).

⁵ A “Fund of Funds Affiliate” is the Adviser, any Sub-Adviser, promoter or principal underwriter of a Fund of Funds, as well as any person controlling, controlled by or under common control with any of those entities. An “Unaffiliated Fund Affiliate” is an investment adviser(s), sponsor, promoter or principal underwriter of any Unaffiliated Fund or any person controlling, controlled by or under common control with any of those entities.

5. With respect to closed-end Underlying Funds, applicants note that although closed-end funds may not be unduly influenced by a holder’s right of redemption, closed-end Underlying Funds may be unduly influenced by a holder’s ability to vote a large block of stock. To address this concern, applicants submit that, with respect to a Fund’s investment in an Unaffiliated Closed-End Investment Company, (i) each member of the Group or Sub-Adviser Group that is an investment company or an issuer that would be an investment company but for section 3(c)(1) or 3(c)(7) of the Act will vote its shares of the Unaffiliated Closed-End Investment Company in the manner prescribed by section 12(d)(1)(E) of the Act and (ii) each other member of the Group or Sub-Adviser Group will vote its shares of the Unaffiliated Closed-End Investment Company in the same proportion as the vote of all other holders of the same type of such Unaffiliated Closed-End Investment Company’s shares. Applicants state that, in this way, an Unaffiliated Closed-End Investment Company will be protected from undue influence by a Fund of Funds through the voting of the Unaffiliated Closed-End Investment Company’s shares.

6. Applicants propose other conditions to limit the potential for undue influence over the Unaffiliated Funds, including that no Fund of Funds or Fund of Funds Affiliate (except to the extent it is acting in its capacity as an investment adviser to an Unaffiliated Investment Company or sponsor to an Unaffiliated Trust) will cause an Unaffiliated Fund to purchase a security in an offering of securities during the existence of any underwriting or selling syndicate of which a principal underwriter is an Underwriting Affiliate (“Affiliated Underwriting”).⁶

7. To further ensure that an Unaffiliated Investment Company understands the implications of a Fund of Funds’ investment under the requested exemptive relief, prior to its investment in the shares of an Unaffiliated Investment Company in excess of the limit of section 12(d)(1)(A)(i) of the Act, a Fund of Funds and the Unaffiliated Investment Company will execute an agreement

⁶ An “Underwriting Affiliate” is a principal underwriter in any underwriting or selling syndicate that is an officer, director, trustee, advisory board member, investment adviser, sub-adviser or employee of the Fund of Funds, or a person of which any such officer, director, trustee, investment adviser, sub-adviser, member of an advisory board or employee is an affiliated person. An Underwriting Affiliate does not include any person whose relationship to an Unaffiliated Fund is covered by section 10(f) of the Act.

stating, without limitation, that each of their boards of directors or trustees (for any entity, the “Board”) and their investment advisers understand the terms and conditions of the order and agree to fulfill their responsibilities under the order (the “Participation Agreement”). Applicants note that an Unaffiliated Investment Company (including an ETF or an Unaffiliated Closed-End Investment Company) would also retain its right to reject any initial investment by a Fund of Funds in excess of the limits in section 12(d)(1)(A)(i) of the Act by declining to execute the Participation Agreement with the Fund of Funds. In addition, an Unaffiliated Investment Company (other than an ETF or closed-end fund whose shares are purchased by a Fund of Funds in the secondary market) will retain its right at all times to reject any investment by a Fund of Funds. Finally, subject solely to the giving of notice to a Fund of Funds and the passage of a reasonable notice period, an Unaffiliated Fund (including an ETF or an Unaffiliated Closed-End Investment Company) could terminate a Participation Agreement with the Fund of Funds.

8. Applicants state that they do not believe that the proposed arrangement will result in excessive layering of fees. The Board of each Fund of Funds, including a majority of the directors who are not “interested persons” within the meaning of section 2(a)(19) of the Act (the “Independent Directors”), will find that the management or advisory fees charged under a Fund of Funds’ advisory contract are based on services provided that are in addition to, rather than duplicative of, services provided under the advisory contract(s) of any Underlying Fund in which the Fund of Funds may invest. In addition, the Adviser will waive fees otherwise payable to it by a Fund of Funds in an amount at least equal to any compensation (including fees received pursuant to any plan adopted by an Unaffiliated Investment Company under rule 12b-1 under the Act) received from an Unaffiliated Fund by the Adviser, or an affiliated person of the Adviser, other than any advisory fees paid to the Adviser or an affiliated person of the Adviser by the Unaffiliated Investment Company, in connection with the investment by the Fund of Funds in the Unaffiliated Fund.

9. Applicants further state that any sales charges and/or service fees charged with respect to shares of a Fund of Funds will not exceed the limits applicable to funds of funds set forth in

rule 2830 of the Conduct Rules of the NASD (“NASD Conduct Rule 2830”).⁷

10. Applicants submit that the proposed arrangement will not create an overly complex fund structure. Applicants note that no Underlying Fund (or, if applicable, its respective master fund) will acquire securities of any other investment company or company relying on section 3(c)(1) or 3(c)(7) of the Act in excess of the limits contained in section 12(d)(1)(A) of the Act, except in certain circumstances identified in condition 12 below.

B. Section 17(a)

1. Section 17(a) of the Act generally prohibits sales or purchases of securities between a registered investment company and any affiliated person, or affiliated person of an affiliated person, of the company. Section 2(a)(3) of the Act defines an “affiliated person” of another person to include (a) any person directly or indirectly owning, controlling, or holding with power to vote, 5% or more of the outstanding voting securities of the other person; (b) any person 5% or more of whose outstanding voting securities are directly or indirectly owned, controlled, or held with power to vote by the other person; and (c) any person directly or indirectly controlling, controlled by, or under common control with the other person.

2. Applicants state that the Funds of Funds and the Affiliated Funds may be deemed to be under the common control of the Adviser and, therefore, affiliated persons of one another. Applicants also state that the Funds of Funds and the Underlying Funds organized as open-end investment companies (“Underlying Open-End Funds”) or UITs (“Underlying UITs”) may also be deemed to be affiliated persons of one another if a Fund of Funds owns 5% or more of the outstanding voting securities of one or more of such Underlying Open-End Funds and/or Underlying UITs. Applicants state that the sale of shares by the Underlying Open-End Funds or Underlying UITs to the Funds of Funds and the purchase of those shares from the Funds of Funds by the Underlying Open-End Funds and/or Underlying UITs (through redemptions) could be deemed to violate section 17(a).⁸

⁷ Any references to NASD Conduct Rule 2830 include any successor or replacement FINRA rule to NASD Conduct Rule 2830.

⁸ Applicants acknowledge that receipt of any compensation by (a) an affiliated person of a Fund of Funds, or an affiliated person of such person, for the purchase by the Fund of Funds of shares of an Underlying Fund or (b) an affiliated person of an Underlying Fund, or an affiliated person of such

3. Section 17(b) of the Act authorizes the Commission to grant an order permitting a transaction otherwise prohibited by section 17(a) if it finds that (i) the terms of the proposed transaction are fair and reasonable and do not involve overreaching on the part of any person concerned; (ii) the proposed transaction is consistent with the policies of each registered investment company concerned; and (iii) the proposed transaction is consistent with the general purposes of the Act. Section 6(c) of the Act permits the Commission to exempt any person or transactions from any provision of the Act if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

4. Applicants submit that the proposed transactions satisfy the standards for relief under sections 17(b) and 6(c) of the Act. Applicants state that the terms of the transactions are reasonable and fair and do not involve overreaching. Applicants state that the terms upon which an Underlying Open-End Fund or Underlying UIT will sell its shares to or purchase its shares from a Fund of Funds will be based on the net asset value of each Underlying Open-End Fund or Underlying UIT.⁹ Applicants also state that the proposed transactions will be consistent with the policies of each Fund of Funds, Underlying Open-End Fund, and

person, for the sale by the Underlying Fund of its shares to a Fund of Funds may be prohibited by section 17(e)(1) of the Act. The Participation Agreement also will include this acknowledgement.

⁹ Applicants note that a Fund of Funds generally would purchase and sell shares of an Underlying Fund that operates as an ETF through secondary market transactions rather than through principal transactions with the Underlying Fund. Applicants nevertheless request relief from sections 17(a)(1) and (2) to permit each Fund of Funds that is an affiliated person, or an affiliated person of an affiliated person, as defined in section 2(a)(3) of the Act, of an ETF to purchase or redeem shares from the ETF. Applicants are not seeking relief from section 17(a) for, and the requested relief will not apply to, transactions where an ETF could be deemed an affiliated person, or an affiliated person of an affiliated person, of a Fund of Funds because an investment adviser to the ETF or an entity controlling, controlled by or under common control with the investment adviser to the ETF is also an investment adviser to the Fund of Funds. Applicants further note that a Fund of Funds will purchase and sell shares of an Underlying Fund that is a closed-end fund (including business development companies) through secondary market transactions at market prices rather than through principal transactions with the closed-end fund (or business development company). Accordingly, applicants are not requesting section 17(a) relief with respect to principal transactions with closed-end funds (including business development companies).

Underlying UIT and with the general purposes of the Act.

C. Other Investments by Section 12(d)(1)(G) Funds

1. Section 12(d)(1)(G) of the Act provides that section 12(d)(1) will not apply to securities of an acquired company purchased by an acquiring company if: (i) The acquiring company and acquired company are part of the same “group of investment companies,” as defined in section 12(d)(1)(G)(ii) of the Act; (ii) the acquiring company holds only securities of acquired companies that are part of the same “group of investment companies,” as defined in section 12(d)(1)(G)(ii) of the Act, government securities, and short-term paper; (iii) the aggregate sales loads and distribution-related fees of the acquiring company and the acquired company are not excessive under rules adopted pursuant to section 22(b) or section 22(c) of the Act by a securities association registered under section 15A of the 1934 Act or by the Commission; and (iv) the acquired company has a policy that prohibits it from acquiring securities of registered open-end management investment companies or registered UITs in reliance on section 12(d)(1)(F) or (G) of the Act.

2. Rule 12d1–2 under the Act permits a registered open-end investment company or a registered UIT that relies on section 12(d)(1)(G) of the Act to acquire, in addition to securities issued by another registered investment company in the same group of investment companies, government securities, and short-term paper: (1) Securities issued by an investment company that is not in the same group of investment companies, when the acquisition is in reliance on section 12(d)(1)(A) or 12(d)(1)(F) of the Act; (2) securities (other than securities issued by an investment company); and (3) securities issued by a money market fund, when the investment is in reliance on rule 12d1–1 under the Act. For the purposes of rule 12d1–2, “securities” means any security as defined in section 2(a)(36) of the Act.

3. Applicants state that the proposed arrangement would comply with rule 12d1–2 under the Act, but for the fact that the Section 12(d)(1)(G) Funds may invest a portion of their assets in Other Investments. Applicants request an order under section 6(c) of the Act for an exemption from rule 12d1–2(a) to allow the Section 12(d)(1)(G) Funds to invest in Other Investments. Applicants assert that permitting a Section 12(d)(1)(G) Fund to invest in Other Investments as described in the application would not raise any of the

concerns that section 12(d)(1) of the Act was intended to address.

4. Consistent with its fiduciary obligations under the Act, a Section 12(d)(1)(G) Fund’s Board will review the advisory fees charged by the Section 12(d)(1)(G) Fund’s investment adviser(s) to ensure that the fees are based on services provided that are in addition to, rather than duplicative of, services provided pursuant to the advisory agreement of any investment company in which the Section 12(d)(1)(G) Fund may invest.

Applicants’ Conditions

A. Investments by Funds of Funds in Underlying Funds

Applicants agree that the order granting the requested relief to permit Funds of Funds to invest in Underlying Funds shall be subject to the following conditions:

1. The members of the Group will not control (individually or in the aggregate) an Unaffiliated Fund within the meaning of section 2(a)(9) of the Act. The members of a Sub-Adviser Group will not control (individually or in the aggregate) an Unaffiliated Fund within the meaning of section 2(a)(9) of the Act. With respect to a Fund’s investment in an Unaffiliated Closed-End Investment Company, (i) each member of the Group or Sub-Adviser Group that is an investment company or an issuer that would be an investment company but for section 3(c)(1) or 3(c)(7) of the Act will vote its shares of the Unaffiliated Closed-End Investment Company in the manner prescribed by section 12(d)(1)(E) of the Act and (ii) each other member of the Group or Sub-Adviser Group will vote its shares of the Unaffiliated Closed-End Investment Company in the same proportion as the vote of all other holders of the same type of such Unaffiliated Closed-End Investment Company’s shares. If, as a result of a decrease in the outstanding voting securities of any other Unaffiliated Fund, the Group or a Sub-Adviser Group, each in the aggregate, becomes a holder of more than 25% of the outstanding voting securities of such Unaffiliated Fund, then the Group or the Sub-Adviser Group will vote its shares of the Unaffiliated Fund in the same proportion as the vote of all other holders of the Unaffiliated Fund’s shares. This condition will not apply to a Sub-Adviser Group with respect to an Unaffiliated Fund for which the Sub-Adviser or a person controlling, controlled by or under common control with the Sub-Adviser acts as the investment adviser within the meaning of section 2(a)(20)(A) of the Act (in the

case of an Unaffiliated Investment Company) or as the sponsor (in the case of an Unaffiliated Trust).

2. No Fund of Funds or Fund of Funds Affiliate will cause any existing or potential investment by the Fund of Funds in an Unaffiliated Fund to influence the terms of any services or transactions between the Fund of Funds or a Fund of Funds Affiliate and the Unaffiliated Fund or an Unaffiliated Fund Affiliate.

3. The Board of each Fund of Funds, including a majority of the Independent Directors, will adopt procedures reasonably designed to ensure that its Adviser and any Sub-Adviser to the Fund of Funds are conducting the investment program of the Fund of Funds without taking into account any consideration received by the Fund of Funds or Fund of Funds Affiliate from an Unaffiliated Investment Company or Unaffiliated Trust or any Unaffiliated Fund Affiliate of such Unaffiliated Investment Company or Unaffiliated Trust in connection with any services or transactions.

4. Once an investment by a Fund of Funds in the securities of an Unaffiliated Investment Company exceeds the limit of section 12(d)(1)(A)(i) of the Act, the Board of the Unaffiliated Investment Company, including a majority of the Independent Directors, will determine that any consideration paid by the Unaffiliated Investment Company to a Fund of Funds or a Fund of Funds Affiliate in connection with any services or transactions: (a) Is fair and reasonable in relation to the nature and quality of the services and benefits received by the Unaffiliated Investment Company; (b) is within the range of consideration that the Unaffiliated Investment Company would be required to pay to another unaffiliated entity in connection with the same services or transactions; and (c) does not involve overreaching on the part of any person concerned. This condition does not apply with respect to any services or transactions between an Unaffiliated Investment Company and its investment adviser(s), or any person controlling, controlled by, or under common control with such investment adviser(s).

5. No Fund of Funds or Fund of Funds Affiliate (except to the extent it is acting in its capacity as an investment adviser to an Unaffiliated Investment Company or sponsor to an Unaffiliated Trust) will cause an Unaffiliated Fund to purchase a security in any Affiliated Underwriting.

6. The Board of an Unaffiliated Investment Company, including a majority of the Independent Directors,

will adopt procedures reasonably designed to monitor any purchases of securities by the Unaffiliated Investment Company in an Affiliated Underwriting once an investment by a Fund of Funds in the securities of the Unaffiliated Investment Company exceeds the limit of section 12(d)(1)(A)(i) of the Act, including any purchases made directly from an Underwriting Affiliate. The Board of the Unaffiliated Investment Company will review these purchases periodically, but no less frequently than annually, to determine whether the purchases were influenced by the investment by the Fund of Funds in the Unaffiliated Investment Company. The Board of the Unaffiliated Investment Company will consider, among other things: (a) Whether the purchases were consistent with the investment objectives and policies of the Unaffiliated Investment Company; (b) how the performance of securities purchased in an Affiliated Underwriting compares to the performance of comparable securities purchased during a comparable period of time in underwritings other than Affiliated Underwritings or to a benchmark such as a comparable market index; and (c) whether the amount of securities purchased by the Unaffiliated Investment Company in Affiliated Underwritings and the amount purchased directly from an Underwriting Affiliate have changed significantly from prior years. The Board of the Unaffiliated Investment Company will take any appropriate actions based on its review, including, if appropriate, the institution of procedures designed to assure that purchases of securities in Affiliated Underwritings are in the best interests of shareholders.

7. Each Unaffiliated Investment Company will maintain and preserve permanently, in an easily accessible place, a written copy of the procedures described in the preceding condition, and any modifications to such procedures, and will maintain and preserve for a period of not less than six years from the end of the fiscal year in which any purchase in an Affiliated Underwriting occurred, the first two years in an easily accessible place, a written record of each purchase of securities in an Affiliated Underwriting once an investment by a Fund of Funds in the securities of an Unaffiliated Investment Company exceeds the limit of section 12(d)(1)(A)(i) of the Act, setting forth (1) the party from whom the securities were acquired, (2) the identity of the underwriting syndicate's members, (3) the terms of the purchase,

and (4) the information or materials upon which the determinations of the Board of the Unaffiliated Investment Company were made.

8. Prior to its investment in shares of an Unaffiliated Investment Company in excess of the limit set forth in section 12(d)(1)(A)(i) of the Act, the Fund of Funds and the Unaffiliated Investment Company will execute a Participation Agreement stating, without limitation, that their Boards and their investment advisers understand the terms and conditions of the order and agree to fulfill their responsibilities under the order. At the time of its investment in shares of an Unaffiliated Investment Company in excess of the limit set forth in section 12(d)(1)(A)(i), a Fund of Funds will notify the Unaffiliated Investment Company of the investment. At such time, the Fund of Funds will also transmit to the Unaffiliated Investment Company a list of the names of each Fund of Funds Affiliate and Underwriting Affiliate. The Fund of Funds will notify the Unaffiliated Investment Company of any changes to the list as soon as reasonably practicable after a change occurs. The Unaffiliated Investment Company and the Fund of Funds will maintain and preserve a copy of the order, the Participation Agreement, and the list with any updated information for the duration of the investment and for a period of not less than six years thereafter, the first two years in an easily accessible place.

9. Before approving any advisory contract under section 15 of the Act, the Board of each Fund of Funds, including a majority of the Independent Directors, shall find that the advisory fees charged under the advisory contract are based on services provided that are in addition to, rather than duplicative of, services provided under the advisory contract(s) of any Underlying Fund in which the Fund of Funds may invest. Such finding, and the basis upon which the finding was made, will be recorded fully in the minute books of the appropriate Fund of Funds.

10. The Adviser will waive fees otherwise payable to it by a Fund of Funds in an amount at least equal to any compensation (including fees received pursuant to any plan adopted by an Unaffiliated Investment Company pursuant to rule 12b-1 under the Act) received from an Unaffiliated Fund by the Adviser, or an affiliated person of the Adviser, other than any advisory fees paid to the Adviser or its affiliated person by the Unaffiliated Investment Company, in connection with the investment by the Fund of Funds in the Unaffiliated Fund. Any Sub-Adviser will waive fees otherwise payable to the

Sub-Adviser, directly or indirectly, by the Fund of Funds in an amount at least equal to any compensation received by the Sub-Adviser, or an affiliated person of the Sub-Adviser, from an Unaffiliated Fund, other than any advisory fees paid to the Sub-Adviser or its affiliated person by the Unaffiliated Investment Company, in connection with the investment by the Fund of Funds in the Unaffiliated Fund made at the direction of the Sub-Adviser. In the event that the Sub-Adviser waives fees, the benefit of the waiver will be passed through to the Fund of Funds.

11. Any sales charges and/or service fees charged with respect to shares of a Fund of Funds will not exceed the limits applicable to funds of funds set forth in NASD Conduct Rule 2830.

12. No Underlying Fund will acquire securities of any other investment company or company relying on section 3(c)(1) or 3(c)(7) of the Act, in excess of the limits contained in section 12(d)(1)(A) of the Act, except to the extent that such Underlying Fund: (a) Acquires such securities in compliance with section 12(d)(1)(E) of the Act and either is an Affiliated Fund or is in the same "group of investment companies" as its corresponding master fund; (b) receives securities of another investment company as a dividend or as a result of a plan of reorganization of a company (other than a plan devised for the purpose of evading section 12(d)(1) of the Act); or (c) acquires (or is deemed to have acquired) securities of another investment company pursuant to exemptive relief from the Commission permitting such Underlying Fund to: (i) Acquire securities of one or more investment companies for short-term cash management purposes or (ii) engage in inter-fund borrowing and lending transactions.

B. Other Investments by Section 12(d)(1)(G) Funds

Applicants agree that the order granting the requested relief to permit Section 12(d)(1)(G) Funds to invest in Other Investments shall be subject to the following condition:

1. Applicants will comply with all provisions of rule 12d1-2 under the Act, except for paragraph (a)(2) to the extent that it restricts any Section 12(d)(1)(G) Fund from investing in Other Investments as described in the application.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Kevin M. O'Neill,
Deputy Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-73544; File No. SR-NYSEMKT-2014-14]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing of Proposed Rule Change Amending Rule 967NY To Enhance the Functionality of the Trade Collar Protection Mechanism

November 6, 2014.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 (the “Act”) ² and Rule 19b-4 thereunder, ³ notice is hereby given that, on October 24, 2014, NYSE MKT LLC (the “Exchange” or “NYSE MKT”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 967NY to enhance the functionality of the trade collar protection mechanism. The text of the proposed rule change is available on the Exchange's Web site at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below,

of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to amend Rule 967NY(a) to clarify and conform with the functionality of the trade collar protection mechanism in use on the Exchange. The Exchange's amendment is to specify (a) how marketable Limit Orders behave when received in a wide market, (b) how subsequently-arriving Market Orders effect collared orders, and (c) the values associated with a Trading Collar. The Exchange also seeks to make non-substantive wording changes to Rule 967NY(a).

Background

Pursuant to Rule 967NY(a), the Exchange applies a “Trade Collar Protection” mechanism that prevents the immediate execution of certain orders at prices outside of a specified parameter (referred to as a “Trading Collar”).⁴ Pursuant to Rule 967NY(a)(3), the Trade Collar Protection mechanism is not available for quotes or for orders with execution conditions IOC, AON, FOK and NOW.

Trading Collars are determined by the Exchange on a class-by-class basis and, unless announced otherwise via Trader Update, are the same value as the bid-ask differential guidelines established pursuant to Rule 925NY(b)(4), as set forth in Rule 967NY(a)(2). For example, Rule 925NY(b)(4) sets the bid-ask differential for an option priced less than \$2.00 at \$0.25. For any option that has a bid less than \$2.00, the Trading Collar will be \$0.25. Accordingly, if the National Best Bid and Offer (“NBBO”) for XYZ is \$0.75 bid and \$1.75 offer, certain orders the Exchange receives will be subject to a \$0.25 Trading Collar.⁵ If necessary to preserve a fair and orderly market, the Exchange may, with the approval of two Trading Officials,⁶ widen or narrow the Trading Collar for one or more option series.

⁴ The Exchange adopted Rule 967NY governing Trade Collar Protection in 2013. See, Exchange Rule 967NY (Securities Exchange Act Release No. 70037) (July 25, 2013), 78 FR 46399 (July 31, 2013) (NYSEMKT-2013-62).

⁵ The bid-ask differential changes as the price increases. Rule 925NY(b)(4) sets the bid-ask differential at no more than \$0.40 where the bid is \$2.00 or more but does not exceed \$5.00. Accordingly, if the NBBO for XYZ is \$3.00 bid and \$3.50 offer, certain orders the Exchange receives will be subject to a \$0.40 Trading Collar Protection.

⁶ A Trading Official, as defined by Rule 900.2NY(82) is an officer or employee of the

Trade Collar Protection applies to two scenarios. First, pursuant to Rule 967NY(a)(1)(i), Trade Collar Protection prevents executions of certain orders when the difference between the National Best Offer (“NBO”) and the National Best Bid (“NBB”) is greater than one Trading Collar. Second, pursuant to Rule 967NY(a)(1)(ii), Trade Collar Protection prevents the execution of the balance of an eligible buy order if it were to execute at a price that is the NBO plus a Trading Collar (or a price that is the NBB minus a Trading Collar for an eligible sell order).

Pursuant to Rule 967NY(a)(1)(i), if the difference between the NBO and the NBB is greater than one Trading Collar, the Exchange will prevent execution or routing of certain orders. Instead, pursuant to Rule 967NY(a)(4)(A), the Exchange will display the order at a price equal to the NBO minus one Trading Collar for sell orders or the NBB plus one Trading Collar for buy orders (the “collared order”). The Exchange will then attempt to execute or route the collared order to buy (sell) against any contra interest priced within one Trading Collar above (below) the displayed price of the collared order.⁷ As set forth in Rule 967NY(a)(4)(C)(iii), should market conditions prevent the order from trading or recalculating for a period of one second, the order will improve its displayed price by an amount equal to an additional Trading Collar.

The collared order will re-price before the expiration of one second as a result of certain changes in the market. Pursuant to Rule 967NY(a)(4)(C)(i), an update to the NBBO (based on another market center or a quote or order on the Exchange) that improves the same side of the market as the collared order will cause the collared order to be redisplayed at the same price as the updated NBBO. In accordance with Rule 967NY(a)(4)(C)(ii), a Limit Order (which is not an IOC Order, AON Order, FOK Order or NOW Order) on the same side of the market priced better than one Trading Collar from the collared order will also become subject to Trade Collar Protection and will cause the collared order to improve by one Trading Collar (which will redisplay at the new price and additional size of the new Limit Order).⁸

Exchange. Trading Officials are not affiliated with ATP Holders.

⁷ See, Rule 967NY(a)(4)(B).

⁸ Rule 967NY(a)(4)(C)(iv) states that a new Market Order on the same side as a collared order will not cause the order subject to Trade Collar Protection to be recalculated (but will redisplay with the additional size of the new Market Order).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

As set forth in Rule 967NY(a)(1)(ii), when the difference between the NBB and NBO is within the bid-ask differential guidelines, orders execute against the NBB or NBO, but Trade Collar Protection prevents execution of the balance of certain order at prices that are a Trading Collar above the NBO for buy orders (or at prices that are a Trading Collar below the NBB for sell orders). Essentially, the Exchange will permit the immediate execution of a Market Order or a marketable Limit Order (together a “marketable order”) up to a Trading Collar away from the NBBO. Pursuant to Rule 967NY(a)(5), the balance of the partially executed order will be subject to Trade Collar Protection and will display at the last sale price. However, if there is an opportunity for trading within one Trading Collar of the last sale price, the order will continue to be displayed at the NBB (NBO) established at the time of the initial execution. Once subject to Trade Collar Protection, the order will follow the re-pricing mechanism described above.

Proposed Change

The Exchange seeks to clarify and correct Rule 967NY so as to conform to current functionality. Pursuant to the language of Rule 967NY(a)(1)(i), the Exchange will prevent the immediately [sic] execution of “Market Orders or marketable Limit Orders” if the width of the bid-ask differential of the NBBO is greater than one Trading Collar. However, during wide market conditions, the Exchange only prevents the immediate execution of Market Orders. Orders with limit prices that are executable against the NBB or NBO, regardless of the width of the bid-ask differential of the NBBO, immediately execute.⁹ The Exchange believes that Market Orders need this additional level of protection as such orders do not suggest that the submitting market participant is aware of the market (or the dislocation associated therewith). Conversely, the Exchange believes that an order with a limit price evidences specific interest at which the submitting market participant is willing to trade. While marketable Limit Orders are immediately executable in situations where the bid-ask differential of the NBBO is greater than one Trading Collar, they nonetheless remain subject to the protections of the Limit Order Filter of 967NY(b).

The Exchange also seeks to delete 967NY(a)(4)(C)(iv), which states that a Market Order that arrives while another order is being displayed due to Trade Collar Protection will join the collared order and display at the same price. While the Exchange believes this behavior beneficial to the market, it has not yet deployed the functionality. While it intends to incorporate such an enhancement in the near future, the Exchange is deleting (a)(4)(C)(iv) in order for its rules to comply with current functionality. Market Orders that arrive while another order is displayed due to Trade Collar Protection will behave in the same manner as later-arriving marketable Limit Orders. Specifically, the later-arriving Market Order will join the already collared order and both will display at a price one Trading Collar above (below) the previous displayed price. The Exchange intends to make another filing to re-establishing the language of (a)(4)(C)(iv) once the functionality is available.

The Exchange also proposes to amend Rule 967NY(a) to add language that clarifies the current operation of the trading collar mechanism. In particular, the Exchange proposes to delete the reference to Rule 925NY(b)(4) and instead codify the values of the Trading Collar directly in Rule 967NY(a). Rule 925NY(b)(4) sets the bid-ask differentials based exclusively on the bid price. The trading collar mechanism employs the same values for determining the Trading Collar. However, while those values are based upon the NBB for buy orders, the value of the Trading Collar for sell orders is based upon the NBO. The Exchange uses the NBB for buy orders because it believes that a market participant who is looking to buy would derive its price off of what other market participants are willing to pay (i.e. the prevailing bid). Similarly, the Exchange uses the NBO for sell orders because it believes that a market participant who is looking to sell would derive its price off of what other market participants are willing to sell (i.e. the prevailing offer). Accordingly, the Exchange proposes new sections (a)(2)(A) and (a)(2)(B) to Rule 967NY, which specifies the values based upon whether the order subject to Trade Collar Protection is to buy or sell.

As an example, the NBBO for XYZ is \$1.00 bid and \$6.00 offer. Based upon Rule 967NY's reference to Rule 925NY(b)(4), it could be interpreted that the Trading Collar would be \$0.25 regardless of whether the Exchange received an order to buy or sell (based upon the bid being less than \$2.00). However, collared sell orders currently derive their Trading Collar and display

price from the NBO. Accordingly, a Market Order to buy would display at \$1.25 (i.e., the \$1.00 NBB plus the \$0.25 Trading Collar (based upon the NBB being less than \$2.00)) and would attempt to execute against any contra interest (on any market) priced \$1.50 or less (i.e., \$1.25 bid plus the \$0.25 Trading Collar). However, a Market Order to sell would display at \$5.50 (i.e., the \$6.00 NBO minus the \$0.50 Trading Collar (based upon the NBO being more than \$5.00 but does not exceed \$10.00)) and would attempt to execute against any contra interest (on any market) priced \$5.00 or greater (i.e., \$5.50 offer minus the \$0.50 Trading Collar).

As a further example, the NBBO for XYZ is \$1.45 × 200 bid and \$2.10 × 200 offer with a \$0.05 MPV. If the Exchange receives a market order to buy 100 contracts, the Trading Collar would be \$0.25 (pursuant to new section (a)(2)(B)(i)). Accordingly, the order will be displayed at \$1.70 (i.e., \$1.45 bid plus the \$0.25 Trading Collar). For a period of one second, the Exchange will attempt to execute the buy order against any contra interest (on any market) priced \$1.95 or less (i.e., \$1.70 plus the \$0.25 Trading Collar). Under Rule 967NY(a)(4)(C)(iii), at the expiration of one second, the Exchange will attempt to redisplay the market buy order subject to Trade Collar Protection at \$1.95 (i.e., \$1.70 plus the \$0.25 Trading Collar). However, since the \$2.10 NBO represents contra interest priced \$2.20 or less (i.e. \$1.95 plus the \$0.25 Trading Collar), the market buy order would execute its 100 contracts against the NBO at \$2.10. In comparison, in the same market for XYZ, if the Exchange receives a market order to sell 100 contracts, the Trading Collar would be \$0.40 (pursuant to new section (a)(2)(B)(ii)). Accordingly, the Exchange will attempt to display the market sell order at \$1.70 (i.e., \$2.10 offer minus the \$0.40 Trading Collar). However, since the \$1.45 NBB represents contra interest priced \$1.45 or greater, (i.e. \$1.70 minus the \$0.25 Trading Collar), the market sell order would execute its 100 contracts against the NBB at \$1.45.

The Exchange also proposes to amend Rule 967NY(a) to strike the extraneous term “inbound” from the rule, which could cause confusion as to when Trade Collar Protection is available because the trade collar mechanism continues to apply to resting orders. In addition, the Exchange proposes to delete the reference in 967NY(a)(3) to the cancellation of IOC Orders, AON Orders, FOK Orders and NOW Orders if not immediately executed, as such is not the behavior of AON Orders. The

⁹ Rule 967NY(a)(4)(C)(ii) and 967NY(b) explain two scenarios where marketable Limit Orders might not immediately execute: (1) When there is already a collared order or (2) when the Limit Order is priced significantly through the contra-side BBO.

Exchange also proposes to capitalize the term “limit order” as used in Rule 967NY(a)(4)(D) to conform with its use in the rest of the rule. Finally, the Exchange proposes to make non-substantive changes to Rule 967NY(a)(4)(C)(i) and (ii) to better clarify behavior in situations where there already exists an already collared order.

2. Statutory Basis

The statutory basis for the proposed rule change is Section 6(b)(5) of the Securities Exchange Act of 1934 (the “Act”), in general, and furthers the objectives of Section 6(b)(5)¹⁰ which requires the rules of an exchange to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. The proposed rule change also is designed to support the principles of Section 11A(a)(1)¹¹ of the Act in that it seeks to assure fair competition among brokers and dealers and among exchange markets. The Exchange believes that the proposed rule amendments relating to the behavior of Limit Orders in a wide market and the effect on Market Orders on already collared orders assist with the maintenance of fair and orderly markets and protects investors by correcting inaccurate language and clarifying existing functionality so that market participants better understand how the Exchange handles certain orders in times of market dislocation. The Exchange also believes that it promotes just and equitable principles of trade to allow marketable Limit Orders received in a wide market to immediately execute against contra-side interest before receiving Trade Collar Protection because Limit Orders provide evidence of prices for which market participants are willing to trade. Accordingly, to the extent contra-side interest exists at the NBBO, the Exchange believes it is appropriate to permit such executions before providing Trade Collar Protection for potential subsequent executions at inferior prices. Furthermore, the Exchange believes that it assists in the fair and orderly market to have Market Orders advance an already collared order in the same fashion as marketable Limit Orders as both are subsequent orders representing executable interest. The Exchange believes that its proposal to clarify that Trading Collar values are based upon the NBB for buy orders and the NBO for

sell orders removes impediments to and perfects the mechanism of a free and open market by basing the Trading Collar upon the benchmark from which a market participant would most likely derive its price. The Exchange recognizes that there could be potential market conditions that result in different Trading Collar values depending on whether the order submitted is to buy or sell. However, the Exchange believes that any such differences are outweighed by meeting the expectations of market participants who submit buy orders based upon the price of the prevailing NBB and sell orders based upon the price of the prevailing NBO. Further, the Exchange believes that clearly setting forth these benchmarks removes impediments to and perfects the mechanism of a free and open market by ensuring that market participants better understand the functionality of the trade collar mechanism on the Exchange and the execution opportunities afforded their orders in certain market conditions. The Exchange also believes that making non-substantive wording changes enhances the description of Trade Collar Protection will add transparency and clarity to the Exchange’s rules.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes the proposal will provide market participants with clarity relating to how the Exchange systems provides protection from anomalous executions. Thus, the Exchange does not believe the proposal creates any significant impact on competition.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

- (A) By order approve or disapprove the proposed rule change, or
- (B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission’s Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NYSEMKT-2014-14 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-NYSEMKT-2014-14. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission’s Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSEMKT-2014-14, and should be submitted on or before December 4, 2014.

¹⁰ 15 U.S.C. 78f(b)(5).

¹¹ 15 U.S.C. 78k-1(a)(1).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹²

Kevin M. O'Neill,
Deputy Secretary.

[FR Doc. 2014-26841 Filed 11-12-14; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-73543; File No. SR-NYSEArca-2014-14]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change Amending Rule 6.60 To Enhance the Functionality of the Trade Collar Protection Mechanism

November 6, 2014.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 (the "Act") ² and Rule 19b-4 thereunder,³ notice is hereby given that, on October 24, 2014, NYSE Arca, Inc. (the "Exchange" or "NYSE Arca") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 6.60 to enhance the functionality of the trade collar protection mechanism. The text of the proposed rule change is available on the Exchange's Web site at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below,

of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to amend Rule 6.60(a) to clarify and conform with the functionality of the trade collar protection mechanism in use on the Exchange. The Exchange's amendment is to specify (a) how marketable Limit Orders behave when received in a wide market, (b) how subsequently-arriving Market Orders effect collared orders, and (c) the values associated with a Trading Collar. The Exchange also seeks to make non-substantive wording changes to Rule 6.60(a) and fix a typographical error in Rule 6.37(b)(1)(E).

Background

Pursuant to Rule 6.60(a), the Exchange applies a "Trade Collar Protection" mechanism that prevents the immediate execution of certain orders at prices outside of a specified parameter (referred to as a "Trading Collar").⁴ Pursuant to Rule 6.60(a)(3), the Trade Collar Protection mechanism is not available for quotes or for orders with execution conditions IOC, AON, FOK and NOW.

Trading Collars are determined by the Exchange on a class-by-class basis and, unless announced otherwise via Trader Update, are the same value as the bid-ask differential guidelines established pursuant to Rule 6.37(b)(1), as set forth in Rule 6.60(a)(2). For example, Rule 6.37(b)(1) sets the bid-ask differential for an option priced less than \$2.00 at \$0.25. For any option that has a bid less than \$2.00, the Trading Collar will be \$0.25. Accordingly, if the National Best Bid and Offer ("NBBO") for XYZ is \$0.75 bid and \$1.75 offer, certain orders the Exchange receives will be subject to a \$0.25 Trading Collar.⁵ If necessary to preserve a fair and orderly market, the Exchange may, with the approval of two Trading Officials,⁶ widen or narrow the

Trading Collar for one or more option series.

Trade Collar Protection applies to two scenarios. First, pursuant to Rule 6.60(a)(1)(i), Trade Collar Protection prevents executions of certain orders when the difference between the National Best Offer ("NBO") and the National Best Bid ("NBB") is greater than one Trading Collar. Second, pursuant to Rule 6.60(a)(1)(ii), Trade Collar Protection prevents the execution of the balance of an eligible buy order if it were to execute at a price that is the NBO plus a Trading Collar (or a price that is the NBB minus a Trading Collar for an eligible sell orders).

Pursuant to Rule 6.60(a)(1)(i), if the difference between the NBO and the NBB is greater than one Trading Collar, the Exchange will prevent execution or routing of certain orders. Instead, pursuant to Rule 6.60(a)(4)(A), the Exchange will display the order at a price equal to the NBO minus one Trading Collar for sell orders or the NBB plus one Trading Collar for buy orders (the "collared order"). The Exchange will then attempt to execute or route the collared order to buy (sell) against any contra interest priced within one Trading Collar above (below) the displayed price of the collared order.⁷ As set forth in Rule 6.60(a)(4)(C)(iii), should market conditions prevent the order from trading or recalculating for a period of one second, the order will improve its displayed price by an amount equal to an additional Trading Collar.

The collared order will re-price before the expiration of one second as a result of certain changes in the market. Pursuant to Rule 6.60(a)(4)(C)(i), an update to the NBBO (based on another market center or a quote or order on the Exchange) that improves the same side of the market as the collared order will cause the collared order to be redisplayed at the same price as the updated NBBO. In accordance with Rule 6.60(a)(4)(C)(ii), a Limit Order (which is not an IOC Order, AON Order, FOK Order or NOW Order) on the same side of the market priced better than one Trading Collar from the collared order will also become subject to Trade Collar Protection and will cause the collared order to improve by one Trading Collar (which will redisplay at the new price and additional size of the new Limit Order).⁸

⁷ See, Rule 6.60(a)(4)(B).

⁸ Rule 6.60(a)(4)(C)(iv) states that a new Market Order on the same side as a collared order will not cause the order subject to Trade Collar Protection to be recalculated (but will redisplay with the additional size of the new Market Order).

¹² 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

⁴ The Exchange adopted Rule 6.60 governing Trade Collar Protection in 2013. See, Exchange Rule 6.60 (Securities Exchange Act Release No. 70038) (July 25, 2013), 78 FR 46392 (July 31, 2013) (NYSEArca-2013-72).

⁵ The bid-ask differential changes as the price increases. Rule 6.37(b)(1) sets the bid-ask differential at no more than \$0.40 where the bid is \$2.00 or more but does not exceed \$5.00. Accordingly, if the NBBO for XYZ is \$3.00 bid and \$3.50 offer, certain orders the Exchange receives will be subject to a \$0.40 Trading Collar Protection.

⁶ A Trading Official, as defined by Rule 6.1(b)(34) is an officer or employee of the Exchange. Trading Officials are not affiliated with OTP Holders.

As set forth in Rule 6.60(a)(1)(ii), when the difference between the NBB and NBO is within the bid-ask differential guidelines, orders execute against the NBB or NBO, but Trade Collar Protection prevents execution of the balance of certain order at prices that are a Trading Collar above the NBO for buy orders (or at prices that are a Trading Collar below the NBB for sell orders). Essentially, the Exchange will permit the immediate execution of a Market Order or a marketable Limit Order (together a “marketable order”) up to a Trading Collar away from the NBBO. Pursuant to Rule 6.60(a)(5), the balance of the partially executed order will be subject to Trade Collar Protection and will display at the last sale price. However, if there is an opportunity for trading within one Trading Collar of the last sale price, the order will continue to be displayed at the NBB (NBO) established at the time of the initial execution. Once subject to Trade Collar Protection, the order will follow the re-pricing mechanism described above.

Proposed Change

The Exchange seeks to clarify and correct Rule 6.60 so as to conform to current functionality. Pursuant to the language of Rule 6.60(a)(1)(i), the Exchange will prevent the immediately [sic] execution of “Market Orders or marketable Limit Orders” if the width of the bid-ask differential of the NBBO is greater than one Trading Collar. However, during wide market conditions, the Exchange only prevents the immediate execution of Market Orders. Orders with limit prices that are executable against the NBB or NBO, regardless of the width of the bid-ask differential of the NBBO, immediately execute.⁹ The Exchange believes that Market Orders need this additional level of protection as such orders do not suggest that the submitting market participant is aware of the market (or the dislocation associated therewith). Conversely, the Exchange believes that an order with a limit price evidences specific interest at which the submitting market participant is willing to trade. While marketable Limit Orders are immediately executable in situations where the bid-ask differential of the NBBO is greater than one Trading Collar, they nonetheless remain subject to the protections of the Limit Order Filter of 6.60(b).

The Exchange also seeks to delete 6.60(a)(4)(C)(iv), which states that a Market Order that arrives while another order is being displayed due to Trade Collar Protection will join the collared order and display at the same price. While the Exchange believes this behavior beneficial to the market, it has not yet deployed the functionality. While it intends to incorporate such an enhancement in the near future, the Exchange is deleting (a)(4)(C)(iv) in order for its rules to comply with current functionality. Market Orders that arrive while another order is displayed due to Trade Collar Protection will behave in the same manner as later-arriving marketable Limit Orders. Specifically, the later-arriving Market Order will join the already collared order and both will display at a price one Trading Collar above (below) the previous displayed price. The Exchange intends to make another filing to re-establishing the language of (a)(4)(C)(iv) once the functionality is available.

The Exchange also proposes to amend Rule 6.60(a) to add language that clarifies the current operation of the trading collar mechanism. In particular, the Exchange proposes to delete the reference to Rule 6.37(b)(1) and instead codify the values of the Trading Collar directly in Rule 6.60(a). Rule 6.37(b)(1) sets the bid-ask differentials based exclusively on the bid price. The trading collar mechanism employs the same values for determining the Trading Collar. However, while those values are based upon the NBB for buy orders, the value of the Trading Collar for sell orders is based upon the NBO. The Exchange uses the NBB for buy orders because it believes that a market participant who is looking to buy would derive its price off of what other market participants are willing to pay (i.e. the prevailing bid). Similarly, the Exchange uses the NBO for sell orders because it believes that a market participant who is looking to sell would derive its price off of what other market participants are willing to sell (i.e. the prevailing offer). Accordingly, the Exchange proposes new sections (a)(2)(A) and (a)(2)(B) to Rule 6.60, which specifies the values based upon whether the order subject to Trade Collar Protection is to buy or sell.

As an example, the NBBO for XYZ is \$1.00 bid and \$6.00 offer. Based upon Rule 6.60's reference to Rule 6.37(b)(1), it could be interpreted that the Trading Collar would be \$0.25 regardless of whether the Exchange received an order to buy or sell (based upon the bid being less than \$2.00). However, collared sell orders currently derive their Trading Collar and display price from the NBO. Accordingly, a Market Order to buy

would display at \$1.25 (i.e., the \$1.00 NBB plus the \$0.25 Trading Collar (based upon the NBB being less than \$2.00)) and would attempt to execute against any contra interest (on any market) priced \$1.50 or less (i.e., \$1.25 bid plus the \$0.25 Trading Collar). However, a Market Order to sell would display at \$5.50 (i.e., the \$6.00 NBO minus the \$0.50 Trading Collar (based upon the NBO being more than \$5.00 but does not exceed \$10.00)) and would attempt to execute against any contra interest (on any market) priced \$5.00 or greater (i.e., \$5.50 offer minus the \$0.50 Trading Collar).

As a further example, the NBBO for XYZ is \$1.45 × 200 bid and \$2.10 × 200 offer with a \$0.05 MPV. If the Exchange receives a market order to buy 100 contracts, the Trading Collar would be \$0.25 (pursuant to new section (a)(2)(B)(i)). Accordingly, the order will be displayed at \$1.70 (i.e., \$1.45 bid plus the \$0.25 Trading Collar). For a period of one second, the Exchange will attempt to execute the buy order against any contra interest (on any market) priced \$1.95 or less (i.e., \$1.70 plus the \$0.25 Trading Collar). Under Rule 6.60(a)(4)(C)(iii), at the expiration of one second, the Exchange will attempt to redisplay the market buy order subject to Trade Collar Protection at \$1.95 (i.e., \$1.70 plus the \$0.25 Trading Collar). However, since the \$2.10 NBO represents contra interest priced \$2.20 or less (i.e. \$1.95 plus the \$0.25 Trading Collar), the market buy order would execute its 100 contracts against the NBO at \$2.10. In comparison, in the same market for XYZ, if the Exchange receives a market order to sell 100 contracts, the Trading Collar would be \$0.40 (pursuant to new section (a)(2)(B)(ii)). Accordingly, the Exchange will attempt to display the market sell order at \$1.70 (i.e., \$2.10 offer minus the \$0.40 Trading Collar). However, since the \$1.45 NBB represents contra interest priced \$1.45 or greater, (i.e. \$1.70 minus the \$0.25 Trading Collar), the market sell order would execute its 100 contracts against the NBB at \$1.45.

The Exchange also proposes to amend Rule 6.60(a) to strike the extraneous term “inbound” from the rule, which could cause confusion as to when Trade Collar Protection is available because the trade collar mechanism continues to apply to resting orders. In addition, the Exchange proposes to delete the reference in 6.60(a)(3) to the cancellation of IOC Orders, AON Orders, FOK Orders and NOW Orders if not immediately executed, as such is not the behavior of AON Orders. The Exchange also proposes to capitalize the term “limit order” as used in Rule

⁹ Rule 6.60(a)(4)(C)(ii) and 6.60(b) explain two scenarios where marketable Limit Orders might not immediately execute: (1) When there is already a collared order or (2) when the Limit Order is priced significantly through the contra-side BBO.

6.60(a)(4)(D) to conform with its use in the rest of the rule. Further, the Exchange proposes to make non-substantive changes to Rule 6.60(a)(4)(C)(i) and (ii) to better clarify behavior in situations where there already exists an already collared order.

Finally, the Exchange seeks to amend Rule 6.37(b)(1)(E) to rectify a typographical error. Specifically, the rule currently states that the bid-ask differentials should be no more than \$1 when the last bid is \$20.10 or more. The rule should instead refer to the last bid being \$20.01 or more.

2. Statutory Basis

The statutory basis for the proposed rule change is Section 6(b)(5) of the Securities Exchange Act of 1934 (the "Act"), in general, and furthers the objectives of Section 6(b)(5)¹⁰ which requires the rules of an exchange to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. The proposed rule change also is designed to support the principles of Section 11A(a)(1)¹¹ of the Act in that it seeks to assure fair competition among brokers and dealers and among exchange markets. The Exchange believes that the proposed rule amendments relating to the behavior of Limit Orders in a wide market and the effect on Market Orders on already collared orders assist with the maintenance of fair and orderly markets and protects investors by correcting inaccurate language and clarifying existing functionality so that market participants better understand how the Exchange handles certain orders in times of market dislocation. The Exchange also believes that it promotes just and equitable principles of trade to allow marketable Limit Orders received in a wide market to immediately execute against contra-side interest before receiving Trade Collar Protection because Limit Orders provide evidence of prices for which market participants are willing to trade. Accordingly, to the extent contra-side interest exists at the NBBO, the Exchange believes it is appropriate to permit such executions before providing Trade Collar Protection for potential subsequent executions at inferior prices. Furthermore, the Exchange believes that it assists in the fair and orderly market to have Market Orders advance an already collared order in the same fashion as marketable Limit Orders as

both are subsequent orders representing executable interest. The Exchange believes that its proposal to clarify that Trading Collar values are based upon the NBB for buy orders and the NBO for sell orders removes impediments to and perfects the mechanism of a free and open market by basing the Trading Collar upon the benchmark from which a market participant would most likely derive its price. The Exchange recognizes that there could be potential market conditions that result in different Trading Collar values depending on whether the order submitted is to buy or sell. However, the Exchange believes that any such differences are outweighed by meeting the expectations of market participants who submit buy orders based upon the price of the prevailing NBB and sell orders based upon the price of the prevailing NBO. Further, the Exchange believes that clearly setting forth these benchmarks removes impediments to and perfects the mechanism of a free and open market by ensuring that market participants better understand the functionality of the trade collar mechanism on the Exchange and the execution opportunities afforded their orders in certain market conditions. The Exchange also believes that making non-substantive wording changes enhances the description of Trade Collar Protection will add transparency and clarity to the Exchange's rules. Finally, the Exchange believes that fixing a typographical error found in Rule 6.37(b)(1)(E) will protect investors and the public interest by reducing confusion that the error would otherwise create.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes the proposal will provide market participants with clarity relating to how the Exchange systems provides protection from anomalous executions. Thus, the Exchange does not believe the proposal creates any significant impact on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

- (A) By order approve or disapprove the proposed rule change, or
- (B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NYSEArca-2014-14 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-NYSEArca-2014-14. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such

¹⁰ 15 U.S.C. 78f(b)(5).

¹¹ 15 U.S.C. 78k-1(a)(1).

filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2014–14, and should be submitted on or before December 4, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹²

Kevin M. O'Neill,
Deputy Secretary.

[FR Doc. 2014–26842 Filed 11–12–14; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73553; File No. SR–NYSE–2014–40]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Amendment No. 1 and Order Granting Accelerated Approval to a Proposed Rule Change, as Modified by Amendment No. 1, To Establish the NYSE Best Quote & Trades Data Feed

November 6, 2014.

I. Introduction

On July 21, 2014, New York Stock Exchange LLC (“NYSE” or the “Exchange”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b–4 thereunder, ² a proposed rule change to establish the NYSE Best Quote & Trades (“NYSE BQT”) data feed. The NYSE BQT data feed would provide a unified view of best bid and offer (“BBO”) and last sale information for the Exchange and its affiliates, NYSE Arca Equities, Inc. (“NYSE Arca”) and NYSE MKT LLC (“NYSE MKT”). The proposed rule change was published for comment in the **Federal Register** on August 8, 2014.³ Two comment letters on the proposal have been received: One letter opposing the proposal,⁴ and a letter from the Exchange responding to the opposing

comment letter.⁵ On September 18, 2014, the Commission extended the time to act on the proposal until November 6, 2014.⁶ On October 31, 2014, the Exchange filed Amendment No. 1 to the proposed rule change.⁷ The Commission is publishing this Notice and Order to solicit comment on Amendment No. 1 and to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

II. Description of the Proposal

The Exchange proposes to establish the NYSE BQT data feed, a data feed consisting of certain data elements from six existing market data feeds: NYSE Trades, NYSE BBO, NYSE Arca Trades, NYSE Arca BBO, NYSE MKT Trades, and NYSE MKT BBO.⁸ The NYSE BQT data feed would have three channels: One channel for the last sale data (the “last sale channel”); another channel for the BBO data (the “best quotes channel”); and a third channel for consolidated volume data (the “consolidated volume channel”).

The last sale channel would provide an aggregation of the same data that is available through NYSE Trades, NYSE Arca Trades, and NYSE MKT Trades.

The best quotes channel would provide the “NYSE BQT BBO,” which would be the best quote from among the NYSE BBO, NYSE Arca BBO, and NYSE MKT BBO based on the following criteria, in order:

⁵ See Letter from Martha Redding, Chief Counsel, NYSE, dated October 31, 2014 (“NYSE Letter”).

⁶ See Securities Exchange Act Release No. 73137, 79 FR 57160 (Nov. 24, 2014).

⁷ In Amendment No. 1, the Exchange modified the proposal to (i) remove language proposing specific fee amounts for NYSE BQT, (ii) clarify that it intended to propose fees that would be no lower than the cost to a vendor of creating a comparable product, including the costs of the underlying feeds, and (iii) represent that it would not offer NYSE BQT until after the proposal has been approved by the Commission, the Exchange has filed fees for NYSE BQT with the Commission, and such fees have become effective. The Commission notes that the Exchange submitted a comment letter attaching Amendment No. 1 on October 31, 2013, and, consequently, Amendment No. 1 is available in the public comment file for SR–NYSE–2014–40 on the Commission’s Web site.

The Exchange has represented that it does not currently offer the NYSE BQT data feed.

⁸ NYSE BBO, NYSE Arca BBO, and NYSE MKT BBO are existing data feeds that distribute on a real-time basis the same BBO information that NYSE, NYSE Arca, and NYSE MKT, respectively, report under the Consolidated Quotation (“CQ”) Plan for inclusion in the CQ Plan’s consolidated quotation information data stream. NYSE Trades, NYSE Arca Trades, and NYSE MKT Trades are existing data feeds that distribute on a real-time basis the same last sale information that NYSE, NYSE Arca, and NYSE MKT, respectively, report under the Consolidated Tape Association (“CTA”) Plan for inclusion in the CTA Plan’s consolidated data streams.

- Price—the exchange with the highest bid or the lowest offer would have overall priority;

- Size—the largest size would take precedence when multiple exchanges submit the same bid or offer price; and

- Time—the earliest time would take precedence when multiple exchanges submit the same bid or offer price with the same sizes.

For each security, the best quotes channel would only include one best bid and one best offer from among the three exchanges. The NYSE BQT BBO would be marked with a market center ID identifying the exchange from which the BBO originated. For example, if XYZ stock were traded on both NYSE and NYSE Arca, and the highest bid and lowest offer according to the NYSE BBO were 1,000 shares at \$10.00 and 1,000 shares at \$10.03, respectively, and the highest bid and lowest offer for XYZ stock according to the NYSE Arca BBO were 1,200 shares at \$9.99 and 900 shares at \$10.02, respectively, then the NYSE BQT data feed would generate the best bid for XYZ stock as 1,000 shares at \$10.00 on NYSE and the best offer as 900 shares at \$10.02 on NYSE Arca.

The consolidated volume channel would carry consolidated volume for all listed equities, which the Exchange would obtain from the securities information processors and then distribute in a manner consistent with the requirements for redistributing such data as set forth in the securities information processor plans.⁹

The NYSE BQT data feed would also provide related data elements, such as trade and security status updates (e.g., trade corrections and trading halts), that are contained in the NYSE Trades, NYSE Arca Trades, and NYSE MKT Trades feeds.

The Exchange proposes to offer the NYSE BQT data feed through the Exchange’s Secure Financial Transaction Infrastructure (“SFTI”) network and market data vendors, as the Exchange does with its other proprietary market data products.

The Exchange has stated that it believes that the NYSE BQT data feed would provide high-quality, comprehensive last sale and BBO data for the Exchange, NYSE Arca, and NYSE MKT in a unified view and would respond to subscriber demand for such a product. The Exchange anticipates that an end user might use the NYSE

⁹ The “securities information processor plans” refer to the CTA Plan and Nasdaq UTP Plan. See Telephone conversations between Leah Mesfin, Special Counsel, Division of Trading and Markets, Commission, and Marija Willen, Chief Counsel of NYSE Group Inc., NYSE (July 30, 2014 and Nov. 6, 2014).

¹² 17 CFR 200.30–3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ See Securities Exchange Act Release No. 72750 (August 4, 2014), 79 FR 46494.

⁴ See Letter from Ira D. Hammerman, General Counsel, SIFMA, to Kevin M. O’Neill, Deputy Secretary, Commission, dated August 28, 2014 (“SIFMA Letter”).

BQT data feed to identify indicative prices for Tape A, B, and C securities through leveraging the depth and breadth of NYSE, NYSE Arca, and NYSE MKT without having to purchase consolidated data, and thus the Exchange believes that the NYSE BQT data feed would not be a latency-sensitive product. The Exchange does not anticipate that an end user would, or could, use the NYSE BQT data feed for purposes of making order-routing or trading decisions. Rather, the Exchange has noted that, under Rule 603 of Regulation NMS, the NYSE BQT data feed could not be substituted for consolidated data in all instances in which consolidated data is used and that certain subscribers would still be required to purchase consolidated data for trading and order-routing purposes.¹⁰

While NYSE, NYSE Arca, and NYSE MKT are the exclusive distributors of the six BBO and Trades feeds from which certain data elements would be taken to create the NYSE BQT data feed, the Exchange has stated that NYSE would not be the exclusive distributor of the aggregated and consolidated information that would compose the proposed NYSE BQT data feed. The Exchange has represented that it would not have any unfair advantage over competing vendors with respect to obtaining data from NYSE, NYSE Arca, and NYSE MKT. In recognition that the Exchange is the source of its own market data and is affiliated with NYSE Arca and NYSE MKT, the Exchange has represented that it will continue to make available all of the individual underlying feeds¹¹ and that the source of the market data it would use to create the proposed NYSE BQT data feed is the same as the source available to other vendors. The Exchange has also represented that other vendors would be able to create a data feed with the same information as proposed for inclusion in the NYSE BQT data feed and to distribute it to clients with no greater latency than the Exchange would be able to distribute the NYSE BQT data feed. In addition, the Exchange has represented that the prices the Exchange would charge clients for the NYSE BQT data feed would not be lower than the cost to a vendor of creating a comparable product, including the cost of receiving the underlying data feeds. Thus, the Exchange has stated, the proposed NYSE BQT data feed would be a data product that a competing vendor could create and sell without being in

a disadvantaged position relative to the Exchange.

With respect to latency, the Exchange, NYSE Arca, and NYSE MKT are located in the same data center in Mahwah, New Jersey. The system creating and supporting the proposed NYSE BQT data feed would need to obtain the six underlying data feeds from these three exchanges before it could aggregate and consolidate information to create the NYSE BQT data feed and then distribute it to end users. After creating the NYSE BQT data feed, the Exchange would distribute this data feed through SFTI and market data vendors. The Exchange also offers third parties access to its data center through co-location. Accordingly, a competing market data vendor wishing to offer a product similar to the NYSE BQT data feed would be able to co-locate at the Exchange's Mahwah, New Jersey facility and obtain the six underlying data feeds.

The Exchange has represented that it has designed the NYSE BQT data feed so that it would not have a competitive advantage over a competing vendor with respect to the speed of access to those six underlying data feeds. Likewise, the Exchange has represented that the NYSE BQT data feed would not have a speed advantage vis-à-vis competing vendors co-located in the data center with respect to access to end-user customers, whether those end users are also co-located or not. The Exchange also has represented that the path for distribution by the Exchange of the NYSE BQT data feed would not be faster than that for distribution by a vendor that independently created a product like the NYSE BQT data feed. The Exchange therefore believes that a market data vendor could perform the aggregation and consolidation function in the Mahwah facility and redistribute a competing product from that location to similarly situated customers on a level playing field with respect to the speed that the Exchange could create and redistribute the NYSE BQT data feed.

With respect to cost, the Exchange has stated that it will file a separate rule filing to establish the fees for the NYSE BQT data feed. To ensure that vendors could compete with the Exchange by creating a product with the same content as the NYSE BQT data feed and selling it to their clients, the Exchange has represented that it would charge its clients for the NYSE BQT data feed an amount at least equal to the cost to a market data vendor to subscribe to the six underlying data feeds, plus an additional amount (to be determined) that would reflect the value of the aggregation and consolidation function

performed by the Exchange. The Exchange therefore believes that a competing vendor could create and offer a product similar to the proposed NYSE BQT data feed at no material cost disadvantage relative to the Exchange. For these reasons, the Exchange believes that vendors could readily offer a product similar to the NYSE BQT data feed on a competitive basis.

The Exchange has stated that it will announce the effective date of the proposed rule change in a notice to be published as soon as practicable following the approval of the proposed rule change by the Commission. The Exchange anticipates making available the NYSE BQT data feed as soon as practicable after approval of the proposed rule change by the Commission and the effectiveness of a rule filing to establish the fees for the NYSE BQT data feed.

III. Summary of Comments

As noted above, the Commission received one comment letter on the proposed rule change, and a letter from the Exchange responding to this commenter.¹² The commenter, SIFMA, generally raised three broad concerns regarding the proposal and urged the Commission to disapprove the filing.

First, SIFMA notes that the Exchange has argued that, because it intends to offer the NYSE BQT data feed in the capacity of a vendor, it does not believe that its proposed data feed is subject to review under the Act. This commenter cites the statement in the proposal that "the Exchange reserves the right to argue, with respect to the NYSE BQT data feed or any other product, that there is no requirement for a filing under Section 19 of the Act to enable the Exchange to offer such products." The commenter disagrees with this view and has argued that selling a combination of data feeds for its various platforms does not make the Exchange a "vendor" in a way that negates its statutory obligations as an SRO. The commenter argues that the Exchange, by relying on a false vendor capacity argument, is attempting to trump its obligations as an SRO and make all of its market data distribution unreviewable. The commenter expresses the concern that this would rob the public of the opportunity to comment afforded under the Act and urges the Commission to ensure that such rule changes are in fact filed with the Commission and subject to public comment and Commission review.

¹⁰ 17 CFR 242.603(c).

¹¹ See NYSE Letter at 2.

¹² See SIFMA Letter and NYSE Letter, *supra* notes 4 and 5.

In its response, NYSE states that although it has reserved the right to argue at another time that there is no requirement for a filing to offer this market data product, it has in fact filed the proposal with the Commission and has sought the Commission's approval to offer the NYSE BQT data feed.

Second, SIFMA argues that the Exchange has failed to file fees for the proposed NYSE BQT data feed that meet the requirements of the Act, including the requirement that such fees be "fair and reasonable" under Section 11A(c)(1)(C) of the Act. The commenter also states that the Exchange has circumvented the requirement to file these fees by marketing the NYSE BQT data feed product for the past 16 months with promotional materials that contain pricing information. SIFMA also argues that the Exchange's proposed markup for the consolidated feed would apply to any vendor that wanted to create a competing product.

In its response letter, NYSE notes that no data recipients are currently receiving the NYSE BQT data feed and that the Exchange has no plans to offer and charge for the NYSE BQT data feed until the appropriate regulatory process has been completed consistent with the Exchange's obligations under the Act. Furthermore, in Amendment No. 1, NYSE has represented that it would not offer the NYSE BQT data feed until after it has filed fees with the Commission for the NYSE BQT data feed and such fees have become effective. NYSE also states that a competing vendor seeking to create a similar unified feed would not need to pay for the NYSE BQT data feed, but would only need to pay for the six underlying feeds. The Exchange has also represented that it would continue to make available all of the individual underlying feeds.

Finally, SIFMA disputes the Exchange's assertion that it is not the exclusive distributor of the NYSE BQT data feed. The commenter argues that the Exchange's vendor contract appears to restrict competition by providing the Exchange with "sole discretion" over the data, particularly with respect to the indirect access service permission that would apply to a competing vendor. The commenter further notes that the contract explicitly prohibits any re-dissemination or other use of its market data. NYSE responds by asserting that the Exchange, NYSE MKT, and NYSE Arca do not contractually restrict vendors from using the underlying data feeds and notes that vendors currently consolidate data products offered by these exchanges, which is permitted under the vendor agreements related to the receipt of market data.

IV. Discussion and Commission Findings

After carefully considering the proposal and the comments submitted, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.¹³ In particular, the Commission finds that the proposed rule change is consistent with the requirements of Section 11A(c)(1)(C) of the Act¹⁴ and with Rule 603(a)(2) of Regulation NMS thereunder,¹⁵ which requires that any national securities exchange, national securities association, broker, or dealer that distributes information with respect to quotations for or transactions in an NMS stock to a securities information processor, broker, dealer, or other persons shall do so on terms that are not unreasonably discriminatory. The Commission also finds that the proposed rule change is consistent with Section 6(b)(5) of the Act, which requires that the rules of an exchange be designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest, and Section 6(b)(8) of the Act, which requires that the rules of an exchange not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.¹⁶

The Commission notes that, to create the NYSE BQT data feed, the Exchange would use underlying data feeds that belong to the Exchange (NYSE BBO and

NYSE Trades) and underlying data feeds that belong to its affiliated exchanges, NYSE Arca and NYSE MKT (NYSE Arca BBO, NYSE Arca Trades, NYSE MKT BBO, and NYSE MKT Trades).

Accordingly, the Commission's review of the Exchange's proposal has focused, in particular, on whether the proposal would result in affiliated exchanges—which are separate self-regulatory organizations under the Act—making their data products or services available to one another at terms (e.g., content, pricing, or latency) that are more favorable than those available to unaffiliated market participants.

The Exchange has represented that the NYSE BQT data feed would be created using underlying data feeds that are available for subscription by market participants. In addition, the Exchange has represented that, as the creator and distributor of the NYSE BQT data feed, it would receive the underlying data feeds from its own systems and from NYSE Arca and NYSE MKT with no latency advantage compared to a competing vendor that wishes to acquire the component feeds in order to offer a competing consolidated data feed. The Exchange, NYSE Arca, and NYSE MKT are located in the same data center in Mahwah, New Jersey, which would be the point at which the Exchange would receive the six underlying data feeds before then aggregating the data to create the NYSE BQT data feed. The Exchange has represented that it offers third parties access to this data center through co-location and that co-located vendors could obtain the same underlying feeds there.¹⁷ The Exchange has also represented that it has designed the NYSE BQT data feed so that it would have no advantages over co-located vendors with respect to the speed of access to the underlying feeds.¹⁸

¹³ In approving this proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

¹⁴ Section 11A(c)(1)(C) of the Act requires, among other things, that no self-regulatory organization, member thereof, securities information processor, broker or dealer make use of the mails or any means or instrumentality of interstate commerce to collect, process, distribute, publish or prepare for distribution or publication any information with respect to quotations for or transactions in any security other than an exempted security in contravention of such rules and regulations as the Commission shall prescribe as necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act to assure that all securities information processors may, for purposes of distribution and publication, obtain on fair and reasonable terms such information with respect to quotations for and transactions in such securities as is collected, processed, or prepared for distribution or publication by an exclusive processor of such information acting in such capacity. 15 U.S.C. 78k-1(c)(1)(C).

¹⁵ 17 CFR 242.603(a)(2).

¹⁶ 15 U.S.C. 78f(b)(5) and (b)(8).

¹⁷ In recognition that the Exchange is the source of its own market data and is affiliated with NYSE Arca and NYSE MKT, the Exchange also has represented that it will continue to make available all of the individual underlying feeds and that the source of the market data it uses to create the proposed NYSE BQT is the same as the source available to other vendors.

¹⁸ The Commission also notes that SIFMA has argued that NYSE is the exclusive processor for NYSE BQT because Exchange's vendor contract appears to restrict competition by asserting that it has "sole discretion" over the use of its data and by prohibiting re-dissemination or other use of its market data. The Commission notes, however, that NYSE has represented that the Exchange, NYSE MKT, and NYSE Arca do not contractually restrict vendors from using the underlying data feeds and that vendors currently consolidate data products offered by these exchanges, which is permitted under the vendor agreements related to the receipt of market data. Based on these representations by the Exchange, the Commission does not believe that

With respect to pricing, although specific fees to be charged for the NYSE BQT data feed are not part of the Exchange's proposal, the Exchange has represented that it will assess a fee that is at least equal to the aggregate cost of the underlying feeds (i.e., at least as much as the cost to a vendor of subscribing to each of the underlying data feeds), plus an additional amount (to be determined) that would reflect the value of the aggregation and consolidation function performed to create the NYSE BQT data feed.¹⁹

Based on the Exchange's representations with respect to the content, latency, and pricing of the NYSE BQT data feed—which are central to the Commission's analysis of the proposal—the Commission finds that the Exchange's proposal is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange. The Commission believes that these representations are designed to ensure that NYSE, NYSE Arca, and NYSE MKT, which are separate self-regulatory organizations, do not, because of their relationship as affiliates, offer one another products or services on a more favorable basis than that available to other competing market participants.

Finally, the Commission notes that SIFMA has objected to the Exchange's characterization of the NYSE BQT data feed as being part of the Exchange's vendor function and outside of the scope of the rule filing process of Section 19(b) of the Act. The Commission believes that a data feed offered by an exchange that contains that exchange's own market data (including a feed that also contains data from other exchanges) is a "material aspect of the operation of the facilities of the self-regulatory organization," and that therefore, such a data product and any related fees are subject to the rule filing process of Section 19(b) of the Act.²⁰

NYSE is the exclusive processor of the data that composes the NYSE BQT feed.

¹⁹ SIFMA has objected to the fact that the Exchange has not included fees in this filing. The Commission notes, however, that the Exchange has stated that it will not offer NYSE BQT until it has submitted the requisite fee filing under Section 19(b) of the Act. The Commission will review any such filing when it has been submitted.

SIFMA has also argued that the Exchange has been actively marketing NYSE BQT for months. The Commission notes, however, that the Exchange has represented that it has not been offering NYSE BQT and that it will not offer this product until fees for it have been filed with the Commission and have become effective.

²⁰ Rule 19b-4 provides that "any material aspect of the operation of the facilities of the self-regulatory organization" is a "stated policy, practice, or interpretation," 17 CFR 240.19b-4(a)(6),

For the foregoing reasons, the Commission finds that the proposed rule change, as amended, is consistent with Section 11A(c)(1)(C) of the Act and Rule 603(a)(2) of Regulation NMS thereunder,²¹ and Sections 6(b)(5) and (b)(8) of the Act.²²

V. Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1

Amendment No. 1 revised the proposal to (i) remove language proposing specific fee amounts for the NYSE BQT data feed, (ii) clarify that the Exchange intends to propose fees that would be no lower than the cost to a vendor of creating a comparable product, including the costs of the underlying feeds, and (iii) represent that the Exchange will not offer the NYSE BQT data feed until after the proposal has been approved by the Commission, the Exchange has filed fees for the NYSE BQT data feed with the Commission, and such fees have become effective. Accordingly, the Commission does not believe that Amendment No. 1 raises any novel regulatory issues and therefore finds that good cause exists to approve the proposal, as modified by Amendment No. 1, on an accelerated basis.

VI. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Amendment No. 1 to the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NYSE-2014-40 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

and that a stated policy, practice of interpretation of a self-regulatory organization is deemed to be a "proposed rule change" unless (1) it is reasonably and fairly implied by an existing rule of the self-regulatory organization or (2) it is concerned solely with the administration of the self-regulatory organization and is not a stated policy, practice or interpretation with respect to the meaning, administration, or enforcement of an existing rule of the self-regulatory organization. 17 CFR 240.19b-4(c).

²¹ 15 U.S.C. 78k-1(c)(1)(C) and 17 CFR 242.603(a)(2).

²² 15 U.S.C. 78f(b)(5) and (b)(8).

All submissions should refer to File Number SR-NYSE-2014-40. This file number should be included on the subject line if email is used.

To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSE-2014-40 and should be submitted on or before December 4, 2014.

VII. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,²³ that the proposed rule change, as modified by Amendment No. 1, (SR-NYSE-2014-40) be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁴

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014-26814 Filed 11-12-14; 8:45 am]

BILLING CODE 8011-01-P

²³ 15 U.S.C. 78s(b)(2).

²⁴ 17 CFR 200.30-3(a)(12).

**SECURITIES AND EXCHANGE
COMMISSION**

[Release No. 34-73550; File No. SR-
NASDAQ-2014-034]

**Self-Regulatory Organizations; The
NASDAQ Stock Market LLC; Notice of
Withdrawal of a Proposed Rule Change
Relating to Proposed Changes To
Remove From the Exchange Rules Fee
Provisions Regarding Re-
Transmission of “Third-Party Data”**

November 6, 2014.

On April 7, 2014, The NASDAQ Stock Market LLC (“Nasdaq” or the “Exchange”) filed with the Securities and Exchange Commission (“Commission”) pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”)¹ and Rule 19b-4 thereunder,² to remove, from the Exchange rules, fee provisions with respect to third-party data feeds that Nasdaq receives from multiple sources and then re-transmits to clients in connection with the Exchange’s co-location services. The proposed rule change was published for comment in the **Federal Register** on April 28, 2014.³ On June 5, 2014, the Commission extended the time to act on the proposal until July 25, 2014.⁴ On July 22, 2014, the Commission instituted proceedings to determine whether to disapprove the proposed rule change in an order published in the **Federal Register**.⁵ The Commission received no comment letters on the proposed rule change. On October 23, 2014, the Commission extended the time to act on the proposal until December 24, 2014.⁶ On October 24, 2014, the Exchange withdrew the proposal (SR-NASDAQ-2014-034).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁷

Kevin M. O’Neill,
Deputy Secretary.

[FR Doc. 2014-26813 Filed 11-12-14; 8:45 am]

BILLING CODE 8011-01-P

**SECURITIES AND EXCHANGE
COMMISSION**

[Release No. 34-73546; File No. SR-Phlx-
2014-67]

**Self-Regulatory Organizations;
NASDAQ OMX PHLX LLC; Notice of
Filing and Immediate Effectiveness of
Proposed Rule Change To Correct Two
Typographical Errors in Rule 3315**

November 6, 2014.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 19b-4 thereunder,² notice is hereby given that on November 4, 2014, NASDAQ OMX PHLX LLC (“Phlx” or “Exchange”) filed with the Securities and Exchange Commission (“SEC” or “Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

**I. Self-Regulatory Organization’s
Statement of the Terms of Substance of
the Proposed Rule Change**

The Exchange is filing with the Commission a proposal to amend NASDAQ OMX PSX (“PSX”)³ Rule 3315 to correct two typographical errors in which references were made to a NASDAQ Stock Market LLC (“NASDAQ”) rule rather than to the PSX rule itself.

The text of the proposed rule change is available on the Exchange’s Web site at <http://nasdaqomxphlx.cchwallstreet.com/>, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

**II. Self-Regulatory Organization’s
Statement of the Purpose of, and
Statutory Basis for, the Proposed Rule
Change**

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ PSX is a facility of Phlx.

*A. Self-Regulatory Organization’s
Statement of the Purpose of, and
Statutory Basis for, the Proposed Rule
Change*

1. Purpose

The purpose of this filing is to correct two typographical errors in PSX Rule 3315(d) in which references were made to a NASDAQ rule rather than the PSX rule itself, and thereby clarify and conform Exchange rules pertaining to error accounts in respect of order routing.

Order routing is currently discussed in PSX Rule 3315. Subsection (d)(2) deals with the maintenance and use of an error account when routing. PSX Rule 3315 was adopted⁴ to fully spell out how routing will work on the Exchange and to generally track the language of NASDAQ Rule 4758. When PSX Rule 3315 was adopted, two references to NASDAQ Rule 4758 were inadvertently left in. In PSX Rule 3315(d)(2)(A) and 3315(d)(2)(B), the intent was and is to make reference to PSX Rule 3315 rather than NASDAQ Rule 4758.

The Exchange is now proposing to correct these two typographical errors. The Exchange is thus substituting the current references to NASDAQ Rule 4758 in subsections (d)(2)(A) and (d)(2)(B) of PSX Rule 3315 with the correct references to PSX Rule 3315. There are no other changes.

The proposed non-substantive change substituting an improper rule reference is done to clarify the order routing rules and eliminate potential confusion, to the benefit of market participants.

2. Statutory Basis

Phlx believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,⁵ in general, and with Sections 6(b)(5) of the Act⁶ in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. This is achieved by correcting two non-substantive typographical errors in PSX Rule 3315, thereby clarifying the order routing rules and eliminating the potential for confusion, to the benefit of

⁴ See Securities Exchange Act Release No. 65469 (October 3, 2011), 76 FR 62486 (October 7, 2011) (SR-Phlx-2011-108) (notice of filing and immediate effectiveness). The goal of the filing was to offer routing strategies on the Exchange that were materially identical to several strategies offered by its affiliate, NASDAQ.

⁵ 15 U.S.C. 78f.

⁶ 15 U.S.C. 78f(b)(5).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 71990 (April 22, 2014), 79 FR 23389 (“Notice”).

⁴ See Securities Exchange Act Release No. 72328, 79 FR 33605 (June 11, 2014).

⁵ See Securities Exchange Act Release No. 72654, 79 FR 43808 (July 28, 2014).

⁶ See Securities Exchange Act Release No. 73416, 79 FR 64444 (October 29, 2014).

⁷ 17 CFR 200.30-3(a)(12).

market participants. The Exchange believes that ensuring the proper rule references in PSX Rule 3315 will promote market participants' understanding of the rule and its administration.

B. Self-Regulatory Organization's Statement on Burden on Competition

Phlx does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of purposes of the Act. The Exchange believes that while rule clarity is generally pro-competitive, the act of clarifying and conforming the two non-substantive typographical errors should have little, if any, impact on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act⁷ and of Rule 19b-4(f)(6) thereunder.⁸

A proposed rule change filed under Rule 19b-4(f)(6)⁹ normally does not become operative prior to 30 days after the date of filing. However, pursuant to Rule 19b-4(f)(6)(iii),¹⁰ the commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay. The Commission believes that waiving the 30-day operative delay could eliminate confusion that may exist if an operative delay was applied to the typographical errors, and believes that waiving the 30-day operative delay is consistent with the protection of investors and the

public interest.¹¹ Therefore, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-PHLX-2014-67 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-PHLX-2014-67. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>).

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE.,

Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-PHLX-2014-67 and should be submitted on or before December 4, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹²

Kevin M. O'Neill,
Deputy Secretary.

[FR Doc. 2014-26810 Filed 11-12-14; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-73542; File No. SR-NYSEMKT-2014-87]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing of Proposed Rule Change Amending the NYSE Amex Options Fee Schedule To Add a Service Fee for Certain Post Trade Adjustments Performed by the Exchange To Be Effective December 1, 2014

November 6, 2014.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on October 28, 2014, NYSE MKT LLC (the "Exchange" or "NYSE MKT") filed with the Securities and Exchange Commission (the "Commission") a proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Amex Options Fee Schedule ("Fee Schedule") to add a service fee for certain post-trade adjustments performed by the Exchange. The Exchange proposes to implement the fee

⁷ 15 U.S.C. 78s(b)(3)(A).

⁸ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

⁹ 17 CFR 240.19b-4(f)(6).

¹⁰ 17 CFR 240.19b-4(f)(6)(iii).

¹¹ For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

¹² 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

change effective December 1, 2014. The text of the proposed rule change is available on the Exchange's Web site at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule to add a service fee for certain post-trade adjustments performed by the Exchange (the "Service Fee"). The Exchange proposes to implement the Service Fee effective December 1, 2014. As described below, the proposed Service Fee would apply to certain post-trade adjustments performed by Exchange staff. The purpose of the proposed Service Fee is to ensure a fair and reasonable use of Exchange resources by allowing the Exchange to recoup for valuable employee time and resources expended on these post-trade adjustments that may also be self-executed by ATP Holders. In addition, the Exchange believes that the proposed Service Fee would incentivize ATP Holders to process their own post-trade adjustments going forward.

In an effort to conserve Exchange resources, the Exchange has provided ATP Holders with the functionality to perform certain of their own post-trade adjustments. Specifically, ATP Holders may perform post-trade adjustments on their side of the trade that do not affect the contractual terms of a transaction. For example, ATP Holders may currently make the following non-contractual post-trade adjustments without Exchange interaction: changing the position indicator (e.g., from Open to Close or Close to Open); adding or removing Clearing Member Trade Agreement ("CMTA") information; allocating trades (e.g., adding multiple

executing domains or "give-ups"); changing the clearing account type (e.g., Customer, Firm, Market Maker) and modifying the optional data field, which may be used by ATP Holders for their own internal back-office processing (collectively, the "Post-Trade Adjustments").

Notwithstanding the availability of functionality for ATP Holders to perform this function themselves, ATP Holders still send the Exchange a significant number of requests, on a daily basis, to perform these straightforward Post-Trade Adjustments on the ATP Holders' behalf. The Exchange uses its best efforts to respond to these requests by ATP Holders in a timely manner. While the Exchange is committed to delivering a certain level of customer service to its ATP Holders, it believes that performing the Post-Trade Adjustments free of charge results in the diversion of valuable Exchange time and resources in a manner that is not a [sic] fair and equitable to either the Exchange or, ultimately the ATP Holders.

Thus, to help offset the costs of having Exchange staff process Post-Trade Adjustments on behalf of ATP Holders, the Exchange is proposing a \$5.00 Service Fee, per trade adjusted. The Post-Trade Adjustments that would be subject to the proposed Service Fee would be only those Post-Trade Adjustments that do not affect the contractual terms of a transaction and that are performed by the Exchange on behalf of ATP Holders when the ATP Holders could otherwise enter the Post-Trade Adjustments on their own behalf.³ The Exchange notes that if an outage or malfunction of an Exchange system makes it infeasible for ATP Holders to enter Post-Trade Adjustments on their own behalf, the Exchange would not assess any Service Fees to process Post-Trade Adjustments on behalf of ATP Holders.

The \$5.00 Service Fee would apply to each trade adjusted, not to each non-contractual change that the Exchange is requested to make to a given trade.⁴ For example, if, for a given trade, an ATP Holder requested that the Exchange change both the position indicator from open to close and at the same time change the CMTA information, the

Service Fee would still be \$5.00, because the changes were for the same trade. The Exchange believes that the \$5.00 Service Fee would reasonably compensate the Exchange for the resources diverted to the Post-Trade Adjustments (i.e., cover employee and overhead expenses). The Exchange also believes that the \$5.00 Service Fee may operate as an effective disincentive for ATP Holders that have relied on the Exchange to perform these services free of charge and believes these ATP Holders may take these tasks in-house given the newly introduced costs.

The Exchange is proposing to discount the \$5.00 fee to \$1.00 per trade adjusted for the first three months that the Service Fee is operative (i.e., December 1, 2014—February 28, 2015). The Exchange believes this temporary discount is reasonable as it would provide ATP Holders time to adjust to the Exchange's new policy. To further provide ATP Holders notice of this proposed change, the Exchange previously announced by Trader Update the specific type of Post-Trade Adjustments that would be subject to the Service Fee.⁵

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,⁶ in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,⁷ in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that the Service Fee is reasonable, equitable and not unfairly discriminatory because it is designed to ensure a fair and reasonable use of Exchange resources by allowing the Exchange to recoup for valuable employee time and resources expended on the Post-Trade Adjustments. The Exchange believes that imposing this \$5.00 fee per trade adjusted would reasonably compensate the Exchange for the resources diverted to the Post-Trade Adjustments (i.e., cover employee and overhead expenses).⁸

Moreover, the Exchange believes that the Service Fee would promote a fair

³ Should the Exchange propose to charge ATP Holders for any additional post-trade adjustments made on behalf of ATP Holders, other than non-contractual changes that ATP Holders may do on their own behalf, the Exchange would only do so pursuant to a separate fee filing.

⁴ The Exchange proposes to add this Service Fee to the Fee Schedule immediately following "Report Fees" under a new section entitled "NYSE AMEX OPTIONS: SERVICE FEES."

⁵ See NYSE Amex Options Trader Update, available here, http://www1.nyse.com/pdfs/NYSE_Amex_Options_Service_Fee_Post_Trade_Adjustments_10_13_14.pdf.

⁶ 15 U.S.C. 78f(b).

⁷ 15 U.S.C. 78f(b)(4) and (5).

⁸ As noted above, the Exchange would offer an introductory rate of \$1.00 per trade adjusted for the first three months that the Service Fee is operational.

and orderly market and protect investors and the public interest because the Service Fee may result in a more efficient use of Exchange resources, which would benefit all market participants.

The Exchange believes that the Service Fee is reasonable, equitable and not unfairly discriminatory because ATP Holders would have the option, as they do today, to perform the Post-Trade Adjustments themselves and the Service Fee would only apply if ATP Holders elected to rely on the Exchange to perform these adjustments for them. Moreover, the Service Fee would apply equally to all market participants who opt to rely on the Exchange to perform the Post-Trade Adjustments. In fact, the Exchange believes that the proposed Service Fee would incentivize ATP Holders to process their own Post-Trade Adjustments going forward.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,⁹ the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule Service Fee is not intended to address any competitive issues among exchanges or ATP Holders but rather to more efficiently use the Exchange's employee time and resources, which may ultimately benefit ATP Holders.

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues, and imposing the Service Fee may enable the Exchange to improve efficiency and ensure the fair and reasonable use of Exchange resources. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed Service Fee reflects this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)¹⁰ of the Act and subparagraph (f)(2) of Rule 19b-4¹¹ thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)¹² of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NYSEMKT-2014-87 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-NYSEMKT-2014-87. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the

Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSEMKT-2014-87, and should be submitted on or before December 4, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹³

Kevin M. O'Neill,

Deputy Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-73545; File No. SR-Phlx-2014-54]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Add a New Complex Order Process Called Legging Orders

November 6, 2014.

I. Introduction

On September 10, 2014, NASDAQ OMX PHLX LLC ("Phlx" or "Exchange") filed with the Securities and Exchange Commission (the "Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to amend its rules governing the trading of complex orders on the Exchange to adopt "legging orders." The proposed rule change was published for comment in the **Federal Register** on September 25, 2014.³ The Commission received no

¹³ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 73152 (September 19, 2014), 79 FR 57632.

⁹ 15 U.S.C. 78f(b)(8).

¹⁰ 15 U.S.C. 78s(b)(3)(A).

¹¹ 17 CFR 240.19b-4(f)(2).

¹² 15 U.S.C. 78s(b)(2)(B).

comment letters regarding the proposed rule change. On November 5, 2014, the Exchange filed Amendment No. 1 to the proposal.⁴ The Commission is publishing this notice to solicit comments on Amendment No. 1 from interested persons and is approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

II. Description

A. Legging Orders

The Exchange proposes to adopt Phlx Rule 1080.08(f)(iii)(C) relating to the generation and execution of “legging orders.” Under the proposal, a legging order is a limit order on the regular order book in an individual series that represents one leg of a two-legged complex order (which improves the cPBBO)⁵ to buy or sell an equal quantity of two option series resting on the Exchange’s Complex Order Book (“CBOOK”).⁶ Phlx proposes that legging orders are firm orders that are included in the Exchange’s displayed best bid or offer.⁷ According to the Exchange, legging orders are designed to increase the opportunity for complex orders to execute by “legging” into the market, whereby all of the legs of the complex order execute against the best bids or offers on the Exchange for the individual options series.⁸

⁴ Amendment No. 1 revises the proposal to: (i) modify proposed Phlx Rule 1080.08(f)(iii)(C)(4)(vi) to provide that, in the event the Exchange receives a PIXL Order for the account of a public customer that is paired with another order for the account of a public customer pursuant to Phlx Rule 1080(n)(vi), the Exchange will remove any resting legging orders in those options series; (ii) add a proposed Phlx Rule 1080.08(f)(iii)(C)(4)(xii) to provide that a legging order will be removed when the legging order is on the Exchange’s book at a price that is not at the minimum increment for that series and that is more aggressive than the same side Phlx Best Bid or Offer (“PBBO”) and an away market moves to lock the PBBO (which is also the NBBO); (iii) provide that the proposal will be implemented within 30 days of Commission approval and that the Exchange will notify members of implementation by issuing an Options Trader Alert; and (iv) the Exchange expects to implement the new functionality on a symbol by symbol bases over the course of a week to mitigate risks associated with the rollout of new technology; and (v) make certain non-substantive clarifications to the rule text.

⁵ According to the Exchange, the term “cPBBO” means the best net debit or credit price for a Complex Order Strategy based on the PBBO for the individual options components of such Complex Order Strategy, and, where the underlying security is a component of the Complex Order, the National Best Bid and/or Offer for the underlying security. See Notice *supra*, note 3, at n.3 (citing Phlx Rule 1080.08(a)(iv)).

⁶ See proposed Phlx Rule 1080.08(f)(iii)(C).

⁷ See *id.* Under the proposal, legging orders are also not routable and are limit orders with a time-in-force of DAY. See *id.*

⁸ See Notice, *supra* note 3, at 57632.

B. Generation of Leg Orders

The Exchange proposes that legging orders may be automatically generated on behalf of Complex Orders resting on the top of the CBOOK so that they are represented at the best bid and/or offer on the Exchange for the individual legs.⁹ Phlx proposes that a legging order may be automatically generated for one leg of a Complex Order at a price: (i) that matches or improves upon the best Phlx displayed bid or offer; and (ii) at which the net price can be achieved when the other leg is executed against the best displayed bid or offer (other than against a legging order).¹⁰ The Exchange proposes not to generate legging orders when the Exchange or a particular option has not opened, is halted or is otherwise not available for trading.¹¹ The Exchange also proposes to not generate a legging order for complex order strategies that are not available for trading.¹²

To determine whether a Legging Order may be generated, the Exchange proposes to evaluate the CBOOK when a Complex Order enters the CBOOK and at a regular time interval to be determined by the Exchange (which interval shall not exceed 1 second) following a change in the National Best Bid/Offer (“NBBO”) or PBBO in any component of a complex order eligible to generate legging orders to determine whether legging orders may be generated.¹³ Under the proposal, a legging order may be generated and executed in an increment other than the minimum increment for that series and will be ranked on the order book at its generated price and displayed at a price that is rounded, down for legging orders to buy and up for legging orders to sell, to the nearest minimum increment allowable for that series.¹⁴

The Exchange proposes to adopt Phlx Rule 1080.08(f)(iii)(C)(2) to provide that legging orders will not be generated if: (i) The price of the legging order would lock or cross the best bid or offer of another exchange; (ii) there is an auction on either side of the market in the series or a “Posting Period” under

⁹ See proposed Phlx Rule 1080.08(f)(iii)(C)(1). The Exchange represents that there can be only one legging order on the same side of the market in a series. See Notice, *supra* note 3, at 57633.

¹⁰ See proposed Phlx Rule 1080.08(f)(iii)(C)(1). See Notice, *supra* note 3, at 57633 for an example of how legging orders would be generated.

¹¹ See proposed Phlx Rule 1080.08(f)(iii)(C)(1).

¹² See *id.*

¹³ See proposed Phlx Rule 1080.08(f)(iii)(C)(1). See also Notice, *supra* note 3, at 57633. Under the proposal, two legging orders relating to the same complex order can be generated, but only one of those can execute as part of the execution of a particular complex order. See *id.*

¹⁴ See proposed Phlx Rule 1080.08(f)(iii)(C)(2).

Phlx Rule 1080(p) regarding “Acceptable Trade Range” on the same side in progress in the series; (iii) the price of the complex order is outside of the Acceptable Complex Execution (“ACE”) Parameter under Phlx Rule 1080.08(i); (iv) there is already a legging order in that series on the same side of the market at the same price (unless it has priority based on the participant type, under existing Exchange rules); (v) the complex order is an all-or-none order; or (vi) the generated legging order for a complex order would immediately cause resting legging orders to be removed pursuant to section proposed Phlx Rule 1080.08(f)(iii)(C)(4)(ix).¹⁵

The Exchange proposes that it may limit the number of legging orders generated on an objective basis and may remove existing legging orders to maintain a fair and orderly market in time of extreme volatility or uncertainty.¹⁶ The Exchange represents that it will determine the options for which, if any, legging orders will be available and will communicate this to its participants.¹⁷ Phlx represents that it would not limit the generation of legging orders on the basis of the entering participant or the participant category of the order (e.g., professional or public customer).¹⁸

C. Execution of Legging Orders

The Exchange proposes that legging orders would be executed only after all other executable orders (including any non-displayed size) and quotes at the same price are executed in full pursuant to the Phlx priority rules applicable to Phlx XL non-Complex Orders, rather than based on the time of receipt of the Complex Order.¹⁹ As a result, the Exchange states the generation of legging orders will not affect the existing priority, or execution opportunities, currently provided to participants in the regular market in any way.²⁰ Under the proposal, when a legging order is executed, the other leg of the complex order will be automatically executed against the displayed best bid or offer on the Exchange and any other legging order based on that complex order will be removed.²¹

Phlx believes that legging orders will provide additional execution opportunities for complex orders without negatively impacting investors

¹⁵ See *id.*

¹⁶ See Notice, *supra* note 3, at 57632–33.

¹⁷ See *id.* at 57633.

¹⁸ See *id.* at n.17.

¹⁹ See proposed Phlx Rule 1080.08(f)(iii)(C)(3) and Notice, *supra* note 3, at 57634.

²⁰ See Notice, *supra* note 3, at 57634.

²¹ See proposed Phlx Rule 1080.08(f)(iii)(C)(3).

in the regular market.²² Phlx also believes that legging orders may facilitate additional executions and enhance execution quality for investors in the regular market by improving the price and/or size of the PBBO and by providing additional execution opportunities for resting orders on the regular book.²³

D. Removal of Legging Orders

The Exchange proposes to adopt Phlx Rule 1080.08(f)(iii)(C)(4) to provide that a legging order will be removed from the Exchange's regular limit order book automatically if: (i) The price of the legging order is no longer at the Exchange's displayed best bid or offer on the regular limit order book; (ii) execution of the legging order would no longer achieve the net price of the complex order when the other leg is executed against the Exchange's best displayed bid or offer on the regular limit order book (other than another legging order); (iii) the complex order is executed in full or in part; (iv) the complex order is cancelled or modified; (v) the price of the complex order is outside of the ACE Parameter of Phlx Rule 1080.08(i); (vi) the Exchange receives a Qualified Contingent Cross Order²⁴ which includes a component in which a legging order exists, an order that will trigger an auction under Phlx rules in a component in which there is a legging order (whether a buy order or a sell order), or a PIXL Order for the account of a public customer paired with an order for the account of a public customer pursuant to Phlx Rule 1080(n)(vi); (vii) a legging order is generated by a different complex order in the same leg at a better price or the same price for a participant with a higher priority; (viii) a complex order is marketable against the cPBBO where a legging order is present and has more than one leg in common with the existing complex order that generated the legging order; (ix) a complex order becomes marketable against multiple legging orders; (x) a complex order consisting of an unequal quantity of components is marketable against the cPBBO where a legging order is present but cannot be executed due to insufficient size in at least one of the components of the cPBBO; (xi) an incoming all-or-none order is entered onto the order book at a price which is equal to or crosses the price of a legging order; or (xii) when the legging order is on the book at a price which is not at the minimum price variation and which

is more aggressive than the same side PBBO, and an away market moves to lock the PBBO (which is also the NBBO).²⁵

Finally, the Exchange proposes to implement the proposed rule change within 30 days of approval by the Commission, and represents that it will notify Exchange members of implementation by issuing an Options Trader Alert.²⁶ The Exchange expects to implement the new functionality on a symbol by symbol basis over the course of a week in order to mitigate risks associated with the rollout of new technology.²⁷

III. Discussion

After careful review, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.²⁸ In particular, the Commission finds that the proposed rule change, as amended, is consistent with Section 6(b)(5) of the Act,²⁹ which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Commission believes that legging orders could facilitate the execution of complex orders resting on the Exchange's CBOOK by increasing the opportunities for eligible complex orders to execute against interest in the regular market on the Exchange's regular order book, thereby benefitting investors seeking to execute complex orders. In addition, the Commission believes that legging orders could benefit participants in the regular market by providing additional liquidity, and potentially more favorable executions, for regular market interest. The Commission notes that it previously approved proposals by other options

exchanges to implement legging orders.³⁰

Under the proposal, legging orders will be firm orders that represent one leg of a two-legged complex order involving a one-to-one ratio resting on the top of the CBOOK.³¹ The Commission notes that, on Phlx, legging orders may be generated and executed in an increment other than the minimum increment for that options series and will be ranked on the order book at its generated price and displayed at a price that is rounded, down for legging orders to buy and up for legging orders to sell, to the nearest minimum increment allowable for that series.³² The Commission also notes that a legging order will be executed only after all other executable orders (including any non-displayed size) and quotes at the same price are executed in full pursuant to the Exchange's priority rules applicable to non-complex orders.³³ Accordingly, the Exchange represents that the generation of a legging order will not affect the existing priority, or execution opportunities, currently provided to market participants in the regular market in any way.³⁴

As noted above, the Exchange represents that it will carefully manage and curtail the number of legging orders being generated so that they do not negatively impact system capacity and performance.³⁵ Phlx represents, further, that it may curtail the number of leg orders on an objective basis, such as by limiting the number of leg orders generated in a particular option, and that it will not limit the generation of leg orders on the basis of the entering participant or the participant category of the order (*i.e.*, professional or public customer).³⁶

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Amendment No. 1 is consistent with the Act. Comments may be submitted by any of the following methods:

³⁰ See Securities Exchange Act Release Nos. 66234 (January 25, 2012), 77 FR 4852 (January 31, 2012) (order approving File No. SR-ISE-2011-82); 69419 (April 19, 2013), 78 FR 24449 (April 25, 2013) (order approving File No. SR-BOX-2013-01); and 69987 (July 15, 2013), 78 FR 43254 (July 19, 2013) (order approving File No. SR-CBOE-2013-026).

³¹ See *infra* note 6 and accompanying text.

³² See *infra* note 14 and accompanying text.

³³ See *infra* note 19 and accompanying text.

³⁴ See *infra* note 20 and accompanying text.

³⁵ See *infra* note 16 and accompanying text.

³⁶ See *infra* note 18 and accompanying text.

²⁵ See proposed Phlx Rule 1080.08(f)(iii)(C)(4). See also Notice, *supra* note 3, at 57634–57636 for examples illustrating the removal of legging orders and *supra* note 4 describing Amendment No. 1 to the proposal.

²⁶ See *supra* note 4 describing Amendment No. 1 to the proposal.

²⁷ See *id.*

²⁸ In approving this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

²⁹ 15 U.S.C. 78f(b)(5).

²² See Notice, *supra* note 3, at 57634.

²³ See Notice, *supra* note 3, at 57637.

²⁴ See Phlx Rule 1080(o).

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-Phlx-2014-54 on the subject line.

Paper Comments

• Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090. All submissions should refer to File Number SR-Phlx-2014-54. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549-1090 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-Phlx-2014-54, and should be submitted on or before December 4, 2014.

V. Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1

The Commission finds good cause for approving the proposed rule change, as amended by Amendment No. 1, prior to the 30th day after the date of publication of notice in the **Federal Register**. Amendment No. 1 revises the proposal to, among other things, provide for two instances whereby the Exchange will remove legging orders to ensure that legging orders are removed when public customer orders are crossed through the Exchange's PIXL auction

pursuant to Phlx Rule 1080(n)(vi) and to ensure that legging orders are removed consistent with Phlx Rule 1084 governing order protection.³⁷ The Commission notes that the revisions are designed to provide market participants with more specificity regarding the operation and implementation of the Exchange's legging order functionality. Accordingly, the Commission finds good cause for approving the proposed rule change, as amended, on an accelerated basis, pursuant to Section 19(b)(2) of the Act.³⁸

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,³⁹ that the proposed rule change (SR-Phlx-2014-54), as amended, be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁴⁰

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014-26809 Filed 11-12-14; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-73540; File No. SR-NASDAQ-2014-099]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Cancel-Replacement and Route Timer

November 6, 2014.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on October 28, 2014, The NASDAQ Stock Market LLC ("NASDAQ" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by NASDAQ. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

NASDAQ proposes to add specificity to the Exchange's options trading rules.

³⁷ See *supra* note 4 for a description of Amendment No. 1.

³⁸ 15 U.S.C. 78s(b)(2).

³⁹ *Id.*

⁴⁰ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

The NASDAQ Options Market ("NOM") is Nasdaq's facility for executing and routing standardized equity and index options. The Exchange proposes to define cancel-replacement orders and also describe a route timer in Chapter VI, entitled "Trading Systems."

The text of the proposed rule change is available on the Exchange's Web site at <http://www.nasdaq.cchwallstreet.com>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, Proposed Rule Change

1. Purpose

The Exchange is proposing to amend Chapter VI to add additional specificity to its rules. The Exchange proposes to amend Section 1, Definitions, to define a cancel-replacement order. The Exchange proposes to amend Section 11, Order Routing, to add greater specificity to the Rulebook concerning a route timer.

Cancel-Replacement Orders

A market participant today has the option of either sending in a cancel order and then separately sending in a new order which serves as a replacement of the original order (two separate messages) or sending a single cancel-replacement order in one message.

If an order is submitted to the System and then subsequently a cancel order is sent to the System cancelling the original order, the original order will be cancelled by the System provided the original order was not already filled partially or in its entirety. A subsequent replacement order would be treated as a new order by the System and will not retain the priority of the cancelled order.

An order that is entered as one single message ("cancel-replacement order")

containing two orders (versus two messages as described above) will also result in the original order being cancelled, provided the original order was not already filled partially or in its entirety.³ The replacement order will be considered a new order by the System and will have time priority as of the time that order is entered into the System, except in the case that the replacement order only serves to reduce the size of the order. A cancel-replacement order which only reduces the size of the order will continue to retain the priority of the original order.⁴ The replacement order will not retain the priority of the cancelled order except when the replacement *reduces* the size of the order and all other terms and conditions are retained. This is similar to the manner in which partially executed orders are prioritized in the System.

By way of example, if the original order is for 600 contracts and a market participant submits a cancel-replacement order for 600 contracts and in doing so, amends a term or condition such as the order type, presuming the original order was not filled in its entirety or partially, the entire original order would be cancelled. If the original order is for 600 contracts and a market participant submits a cancel-replacement order for 600 contracts and in doing so, amends a term or condition such as the order type, and 600 contracts were already filled, the cancel-replacement order would be returned to the market participant. If the original order is for 600 contracts and a market participant submits a cancel-replacement order for 600 contracts and in doing so, amends a term or condition such as the order type, and 300 contracts were already filled, the order would be modified to 300 contracts. Finally, if the original order is for 600 contracts and a market participant submits a cancel-replacement order solely reducing the size of the order by 300 contracts, the order would be modified to 300 contracts and the original order would retain its priority. In the previous examples provided, the orders would not retain the priority of the original orders.

The Exchange proposes to add the following definition in Chapter VI,

³ With cancel-replacement orders, the original order is automatically canceled or reduced by the number of contracts that were executed depending on the volume of the original order that was filled. The market participant is required to enter the original order reference number when a cancel-replacement order is sent to the System as one message.

⁴ When a cancel-replacement order is sent to the System as one message the original order number reference is maintained by the System.

Section 1, “Cancel-replacement order shall mean a single message for the immediate cancellation of a previously received order and the replacement of that order with a new order with new terms and conditions. If the previously placed order is already filled partially or in its entirety, the replacement order is automatically canceled or reduced by the number of contracts that were executed. The replacement order will not retain the priority of the cancelled order except when the replacement order reduces the size of the order and all other terms and conditions are retained.” This language is being added to Section 1(e)(1) to reflect the manner in which cancel-replacement orders function today. This filing does not reflect a change to the System; rather, the Exchange is memorializing in its rules the manner in which cancel-replacement orders are treated today.

Route Timer

Today, the System provides a number of routing options pursuant to which orders are sent to other available market centers for potential execution, per the entering market participant’s instructions.⁵ The System routing options are SEEK or SRCH. With SEEK and SRCH, an order will first check the System for available contracts for execution. After checking the System for available contracts, orders are sent to other available market centers for potential execution, per the entering firm’s instructions.

The Exchange proposes to add language in a new Section 11(a)(1)(C) to specify that after an order is initially routed,⁶ pursuant to either the SEEK or SRCH routing option, the order will post to the book and will be routed after a time period (“Route Timer”) not to exceed one second as specified by the Exchange on its Web site provided that the order’s limit price would lock or cross other market center(s).⁷ If, during the Route Timer, any new interest arrives opposite the order that is equal to or better than the away best bid or offer (“ABBO”) price, the order will trade against such new interest at the ABBO price. Eligible unexecuted orders will be routed at the end of the Route

⁵ Participants can designate orders as either available for routing or not available for routing. See Chapter VI, Sec. 11(a).

⁶ If an order is only partially routed the portion that was not routed will be posted to the book.

⁷ Pursuant to Section 11(c) of Chapter VI, orders sent by the System pursuant to the SEEK and SRCH routing options to other markets would not retain time priority with respect to other orders in the System. If an order routed pursuant to SEEK or SRCH is subsequently returned, in whole or in part, that order, or its remainder, will receive a new time stamp reflecting the time of its return to the System.

Timer provided the order was not filled and the order’s limit price would continue to lock or cross the ABBO. If an order was routed with either the SEEK or SRCH routing option, and has size after such routing, it will execute against contra side interest in the book, post in the book, and route again pursuant to the process described above, if applicable, if the order’s limit price would lock or cross another market center(s).

This language is being added to Section 11 to reflect the manner in which the Exchange imposes a Route Timer on routed orders today to permit quote updates to occur prior to subsequent routing. This filing does not reflect a change to the System, rather the Exchange is memorializing in its rules the manner in which orders are routed today.

The Exchange also proposes to amend rule text in Section 11(a)(1)(A) of Chapter VI concerning the SEEK routing option. The Exchange proposes to add language which clarifies the differences between SEEK and SRCH routing options with respect to contracts that remain un-executed after routing and are posted on the book. The Exchange proposes to state, “Once on the book *at the limit price*, should the order subsequently be locked or crossed by another market center, the System will not route the order to the locking or crossing market center.” The Exchange believes this language more clearly differentiates an order routed pursuant to SEEK as compared to the SRCH routing option. An order routed pursuant to the SEEK routing option is routable until it is posted at its limit price. Once posted at its limit price, an order routed pursuant to the SEEK routing option would not continue to route, as compared to an order routed pursuant to the SRCH routing option. An order routed pursuant to the SRCH routing option is routable for the life of the order. The routing functionality is similar to functionality currently on Phlx.⁸

The Exchange also proposes to correct a typographical error in Chapter VI, Section 11(a)(1).

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act⁹ in general, and furthers the objectives of Section 6(b)(5) of the Act¹⁰ in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and

⁸ See Phlx Rule 1080(m).

⁹ 15 U.S.C. 78f(b).

¹⁰ 15 U.S.C. 78f(b)(5).

equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that its proposal to define cancel-replacement orders will add transparency to the rules. The Exchange is not amending the manner in which the System handles these orders. The Exchange is memorializing, in its rules, the method by which orders are handled by the System. The Exchange is defining cancel-replacement orders within Chapter VI, Section 1.

Specifically, with respect to cancel-replacement orders that reduce size, the Exchange believes that allowing cancel-replacement orders where only size is reduced to retain the priority of the original order is consistent with the manner in which the Exchange treats partially executed orders, which similarly apply the priority of the executed portion of the order to the remaining portion of the order. In addition, by permitting market participants' orders to remain on the book with the original priority and reduced size, the Exchange is providing market participants an ability to reduce exposure. The Exchange believes that adding transparency and specificity to the Rules protects investors and the public interest by reducing the potential for investor confusion.

The Exchange is also memorializing the manner in which the Exchange routes unexecuted portions of an order that will be subsequently routed to other markets when it comes back and subsequently locks and/or crosses the market. The Exchange will continue to re-route eligible unexecuted orders pursuant to a Route Timer. Contracts which remain unexecuted will be posted to the book provided the order's limit price would not lock or cross the ABBO. Specifically, the Exchange is describing the Route Timer that applies to eligible unexecuted portions of an order which will be subsequently routed. The timer protects investors and the public interest by providing a brief time period to allow the opportunity for markets to update quotes prior to subsequent routes.

The Exchange seeks to add language concerning the specific manner in which the Exchange will handle the routed order by specifying the routing methods in which SEEK or SRCH orders will route to the away market(s). The Exchange is adding clarifying language

to make clear that after an order is initially routed, pursuant to either the SEEK or SRCH routing option, the order will post to the book and will be routed after a time period ("Route Timer") not to exceed one second as specified by the Exchange on its Web site provided that the order would lock or cross other market center(s). If, during the Route Timer, any new interest arrives opposite the order that is equal to or better than the ABBO price, the order will trade against such new interest at the ABBO price. Eligible unexecuted orders will be routed at the end of the Route Timer provided the order was not filled and it would continue to lock or cross the ABBO. If an order was routed with either the SEEK or SRCH routing option, and has size after such routing, it will execute against contra side interest in the book, post in the book, and route again pursuant to the process described above, if applicable, if the order would lock or cross another market center(s).

Further, the proposal to amend rule text in Section 11(a)(1)(A) of Chapter VI concerning SEEK orders clarifies the differences between SEEK and SRCH routing options with respect to contracts that remain un-executed after routing and are posted on the book. The Exchange seeks to clearly note that once an order routed pursuant to the SEEK routing option is on the order book at the limit price, it will not route, despite the order locking or crossing another market center. The Exchange believes this language more clearly differentiates an order routed pursuant to the SEEK routing option as compared to SRCH routing option.

The Exchange believes this language adds specificity and detail to the rule text so that market participants may anticipate the manner in which orders are handled by the Exchange when routing. The Exchange believes that adding transparency and specificity to the Rules protects investors and the public interest by reducing the potential for investor confusion.

The Exchange's proposal is intended to provide additional specificity to the rules in the manner in which the System treats cancel-replacement orders and handles routing of eligible unexecuted portions of previously routed orders, which is designed to promote just and equitable principles of trade.

The Exchange is not proposing to amend the manner in which the System operates. Cancel-replacement orders have been treated in this fashion since NOM was first launched. Further, the Routing Timer for subsequent routes has also been in place on NOM since its launch. The Exchange is proposing

these additions to the rules in order to provide greater specificity to the Exchange's rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange is seeking to provide greater transparency in its rules. The amendments are non-substantive and would apply to all market participants in the same manner. Permitting cancel-replacement orders to retain their original priority does not impose a burden on competition because the priority is retained only in the instance that size alone is changed and only if it is reduced. Permitting all market participants to reduce their exposure without penalty does not burden competition, rather it promotes competition by allowing participants the ability to change their orders in a changing market, provided the order was not already partially filled or filled in its entirety.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act¹¹ and subparagraph (f)(6) of Rule 19b-4 thereunder.¹²

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved. The Exchange has provided the Commission

¹¹ 15 U.S.C. 78s(b)(3)(a)(ii).

¹² 17 CFR 240.19b-4(f)(6).

written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NASDAQ-2014-099 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549.

All submissions should refer to File Number SR-NASDAQ-2014-099. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of NASDAQ. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NASDAQ-2014-099 and should be

submitted on or before December 4, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹³

Kevin M. O'Neill,

Deputy Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-73548; File No. SR-Phlx-2014-68]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Routing Fees

November 6, 2014.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on October 30, 2014, NASDAQ OMX PHLX LLC ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify Section V entitled "Routing Fees" of the NASDAQ OMX Phlx LLC Pricing Schedule ("Pricing Schedule"). Specifically, the Exchange proposes to modify Section V entitled "Routing Fees" of the Phlx Pricing Schedule ("Pricing Schedule"). Specifically, the Exchange proposes to amend its Routing Fees, and to allow aggregation of Customer³ volume for calculating discount thresholds and receiving discounted routing fees.

While the changes proposed herein are effective upon filing, the Exchange has designated that the amendments be operative on November 3, 2014.

¹³ 17 CFR 200.30-3(a)(12).

¹⁴ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ The term "Customer" applies to any transaction that is identified by a Participant for clearing in the Customer range at The Options Clearing Corporation ("OCC") which is not for the account of broker or dealer or for the account of a "Professional" (as that term is defined in Rule 1000(b)(14)). Section V of Pricing Schedule.

The text of the proposed rule change is available on the Exchange's Web site at <http://nasdaqomxphlx.cchwallstreet.com/>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to amend the Routing Fees in Section V of the Pricing Schedule in order to recoup costs incurred by the Exchange to route orders to away markets, and to allow members and member organizations to aggregate their Customer volume for calculating discount thresholds and receiving discounted routing fees.

Today, the Exchange assesses a Non-Customer a \$0.97 per contract Routing Fee to any options exchange for routing an order. The Customer Routing Fee for option orders routed to The NASDAQ Options Market, LLC ("NOM") is a \$0.12 per contract Fixed Fee ("Fixed Fee") in addition to the actual transaction fee assessed. The Customer Routing Fee for option orders routed to NASDAQ OMX BX, Inc. ("BX Options") is \$0.12 per contract. The Customer Routing Fee for option orders routed to all other options exchanges⁴ (excluding NOM and BX Options) is a fixed fee of \$0.22 per contract in addition to the actual transaction fee assessed. If the away market pays a rebate, the Routing Fee is \$0.12 per contract.

With respect to the fixed costs, the Exchange incurs a fee when it utilizes

⁴ This includes BATS Exchange, Inc. ("BATS"), BOX Options Exchange LLC ("BOX"), the Chicago Board Options Exchange, Incorporated ("CBOE"), C2 Options Exchange, Incorporated ("C2"), International Securities Exchange, LLC ("ISE"), the Miami International Securities Exchange, LLC ("MIAX"), NYSE Arca, Inc. ("NYSE Arca"), NYSE MKT LLC ("NYSE Amex") and ISE Gemini, LLC ("Gemini").

NASDAQ Execution Services LLC (“NES”), a member of the Exchange and the Exchange’s affiliated broker-dealer exclusive order router.⁵ Each time NES routes an order to an away market, NES is charged a clearing fee⁶ and, in the case of certain exchanges, a transaction fee is also charged in certain symbols, which fees are passed through to the Exchange. The Exchange currently recoups clearing and transaction charges incurred by the Exchange as well as certain other costs incurred by the Exchange when routing to away markets, such as administrative and technical costs associated with operating NES, membership fees at away markets, Options Regulatory Fees (“ORFs”), staffing and technical costs associated with routing options. The Exchange assesses the actual away market fee at the time that the order was entered into the Exchange’s trading system. This transaction fee is calculated on an order-by-order basis since different away markets charge different amounts.

The Exchange is proposing to increase its Non-Customer Routing Fees from \$0.97 to \$0.99 per contract to any options exchange. The Exchange is proposing to increase its Customer Routing Fixed Fees to NOM from \$0.12 to \$0.13 per contract, in addition to the actual transaction fee assessed to recoup an additional portion of the costs incurred by the Exchange for routing these orders. The Exchange is proposing to increase its Customer Routing Fixed Fees to BX Options from \$0.12 to \$0.13 per contract. The Exchange is proposing to increase its Customer Routing Fixed Fees to all other options exchanges (excluding NOM and BX Options) from \$0.22 to \$0.23 per contract, in addition to actual transaction fees assessed. The Exchange would also increase the Customer Routing Fee to all other options exchanges if the away market pays a rebate from a fee of \$0.12 to \$0.13 per contract, because the Exchange would continue to retain the rebate to offset the cost to route orders to offset the cost to route orders to these away markets. The Exchange desires to recoup additional costs at this time.

Today, a member organization that:

- (1) Qualifies for a Tier 2, 3, 4 or 5 rebate in the Customer Rebate Program in Section B of the Pricing Schedule; and
- (2) routes away more than 5,000 Customer contracts per day in a given

month to an away market (together the “Customer Rebate requirements”)⁷ is entitled to receive a credit equal to the applicable Fixed Fee plus \$0.05 per contract, unless the away market transaction fee is \$0.00 or the away market pays a rebate, in which case the member organization is entitled to receive a credit equal to the applicable Fixed Fee. Customer rebates are paid on Customer Rebate Tiers in Section B of the Pricing Schedule according to applicable categories (A or B). The Customer Rebate Tiers are calculated by totaling Customer volume in Multiply Listed Options (including SPY) that are electronically-delivered and executed, except volume associated with electronic Qualified Contingent Cross (“QCC”) Orders, as defined in Rule 1080(o), in a month.

The Exchange is proposing to add language to Section V stating that members and member organizations under Common Ownership⁸ may aggregate their Customer volume routed away for purposes of calculating discount thresholds⁹ and receiving discounted routing fees. The Customer Rebate requirements regarding Tier and volume remain in place. However, with the added language if members and member organizations are under Common Ownership they will be able to aggregate their Customer volume for the purpose of calculating discount thresholds and receiving discounted routing fees.

The proposal allows the Exchange to continue attracting liquidity to Phlx while recouping costs incurred by the Exchange to route orders to away markets.

2. Statutory Basis

The Exchange believes that its proposal to amend the Pricing Schedule is consistent with Section 6(b) of the Act¹⁰ in general, and furthers the objectives of Section 6(b)(4) and (b)(5) of the Act¹¹ in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges

among members and issuers and other persons using any facility or system which Phlx operates or controls, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that amending the Non-Customer Routing Fee for orders routed to any options exchange from a fee of \$0.97 to \$0.99 per contract, is reasonable because the Exchange desires to recoup an additional portion of the cost it incurs when routing Non-Customer orders. The Exchange is proposing to increase the Fixed Fee to recoup additional costs that are incurred by the Exchange in connection with routing these orders on behalf of its members.

The Exchange believes that amending the Customer Routing Fee for orders routed to NOM from a Fixed Fee of \$0.12 to \$0.13 per contract, in addition to the actual transaction fee, is reasonable because the Exchange desires to recoup an additional portion of the cost it incurs when routing Customer orders to NOM. Today, the Exchange assesses orders routed to NOM a lower Fixed Fee for routing Customer orders as compared to the Fixed Fee assessed to other options exchanges. The Exchange is proposing to increase the Fixed Fee to recoup additional costs that are incurred by the Exchange in connection with routing these orders on behalf of its members.

The Exchange believes that amending the Customer Routing Fee for orders routed to BX Options from a Fixed Fee of \$0.12 to \$0.13 per contract is reasonable because the Exchange desires to recoup an additional portion of the cost it incurs when routing Customer orders to BX Options, similar to the amount of Fixed Fee it proposes to assess for orders routed to NOM. The Exchange is proposing to assess a Fixed Fee to recoup additional costs that are incurred by the Exchange in connection with routing these orders on behalf of its members. While the Exchange would continue to retain any rebate paid by BX Options,¹² the Exchange does not assess the actual transaction fee that is charged by BX Options for Customer orders.

The Exchange believes that continuing to assess lower Fixed Fees to route Customer orders to NOM and BX Options, as compared to other options exchanges, is reasonable as the Exchange is able to leverage certain infrastructure to offer those markets

⁵ See Securities Exchange Act Release No. 71416 (January 28, 2014), 79 FR 6244 (February 3, 2014) (SR-Phlx-2014-05) (notice of filing and immediate effectiveness regarding utilization of NES for outbound order routing from Phlx).

⁶ The Options Clearing Corporation (“OCC”) assesses \$0.01 per contract side.

⁷ When the Exchange recently added the 5,000 Customer contracts criterion, it did so to provide a credit to member organizations that qualify for a Customer rebate and route away a certain amount of volume. See Securities Exchange Act Release No. 71258 (January 8, 2014), 79 FR 2948 (January 14, 2014) (SR-Phlx-2013-125) (notice of filing and immediate effectiveness).

⁸ The term “Common Ownership” shall mean members or member organizations under 75% common ownership or control. Section V of Pricing Schedule.

⁹ A member or member organization may, for example, route away more than 5,000 Customer contracts per day in a given month to an away market.

¹⁰ 15 U.S.C. 78f(b).

¹¹ 15 U.S.C. 78f(b)(4), (5).

¹² BX Options pays a Customer Rebate to Remove Liquidity as follows: Customers are paid \$0.35 per contract in All Other Penny Pilot Options (excluding BAC, IWM, QQQ, SPY and VXX) and \$0.70 per contract in Non-Penny Pilot Options. See BX Options Rules at Chapter XV, Section 2(1).

lower fees as explained further below. Similarly, the Exchange believes that amending the Customer Routing Fee to other away markets, other than NOM and BX Options, in the instance the away market does not pay a rebate from a Fixed Fee of \$0.22 to \$0.23 per contract is reasonable because the Exchange desires to recoup an additional portion of the cost it incurs when routing orders to these away markets. While the Exchange would continue to retain any rebate paid by these [sic] away markets, the Exchange does not assess the actual transaction fee that is charged by the away market for Customer orders. The Fixed Fee for Customer orders is an approximation of the costs the Exchange will be charged for routing orders to away markets. As a general matter, the Exchange believes that the proposed fees for Customer orders routed to markets which pay a rebate, such as BX Options and other away markets, would allow it to recoup and cover a portion of the costs of providing optional routing services for Customer orders because it better approximates the costs incurred by the Exchange for routing such orders. While each destination market's transaction charge varies and there is a cost incurred by the Exchange when routing orders to away markets, including, OCC clearing costs, administrative and technical costs associated with operating NES, membership fees at away markets, ORFs and technical costs associated with routing options, the Exchange believes that the proposed Routing Fees will enable it to recover the costs it incurs to route Customer orders to away markets.

Moreover, the Exchange believes that amending the Customer Routing Fee to other away markets, other than NOM and BX Options, if the away market pays a rebate, from \$0.12 to \$0.13 per contract is reasonable because the Exchange desires to recoup an additional portion of the cost it incurs when routing Customer orders to away markets, similar to the amount of Fixed Fee it proposes to assess for orders routed to NOM and BX Options. The Exchange is proposing to assess a Fixed Fee to recoup additional costs that are incurred by the Exchange in connection with routing these orders on behalf of its members. While the Exchange would continue to retain any rebate paid by away markets, the Exchange does not assess the actual transaction fee that is charged by away markets for Customer orders.

The Exchange believes that amending the Non-Customer Routing Fee for orders routed to any options exchange from a fee of \$0.97 to \$0.99 per contract,

is equitable and not unfairly discriminatory because the Exchange would assess the same \$0.99 per contract fee to all market participants utilizing routing for Non-Customer orders.

The Exchange believes that amending the Customer Routing Fee for orders routed to NOM from a Fixed Fee of \$0.12 to \$0.13 per contract, in addition to the actual transaction fee, is equitable and not unfairly discriminatory because the Exchange would assess the same Fixed Fee to all orders routed to NOM in addition to the transaction fee assessed by that market.

The Exchange believes that increasing the Customer Routing Fee for orders routed to BX Options from a Fixed Fee from \$0.12 to \$0.13 per contract is equitable and not unfairly discriminatory because the Exchange would uniformly increase the Fixed Fee, similar to NOM, for all orders routed to BX Options and would continue to uniformly not assess the actual transaction fee, as is the case today.

The Exchange would uniformly assess a \$0.13 per contract Fixed Fee to orders routed to NASDAQ OMX exchanges because the Exchange is passing along the saving realized by leveraging NASDAQ OMX's infrastructure and scale to market participants when those orders are routed to NOM or BX Options and is providing those saving to all market participants. Furthermore, it is important to note that when orders are routed to an away market they are routed based on price first.¹³ The Exchange believes that it is equitable and not unfairly discriminatory to assess a fixed cost of \$0.13 per contract to route orders to NOM and BX Options because the cost, in terms of actual cash outlays, to the Exchange to route to those markets is lower. For example, costs related to routing to NOM and BX Options are lower as compared to other away markets because NES is utilized by all three exchanges to route orders.¹⁴ NES and the three NASDAQ OMX options markets have a common data center and staff that are responsible for the day-to-day operations of NES. Because the three exchanges are in a common data center, Routing Fees are reduced because costly expenses related to, for example, telecommunication lines to obtain connectivity are avoided when routing orders in this instance. The costs related to connectivity to route orders to other NASDAQ OMX exchanges are lower than the costs to route to a non-NASDAQ OMX

exchange. When routing orders to non-NASDAQ OMX exchanges, the Exchange incurs costly connectivity charges related to telecommunication lines, membership and access fees, and other related costs when routing orders.

The Exchange believes that amending the Customer Routing Fee to other away markets, other than NOM and BX Options, in the instance the away market does not pay a rebate from a Fixed Fee of \$0.22 to \$0.23 per contract is equitable and not unfairly discriminatory because the Exchange would assess the same Fixed Fee to all orders routed to away markets other than NOM and BX Options in addition to the transaction fee. The Exchange's proposal to increase the Customer Routing Fee to all other options exchanges that pay a rebate, other than NOM and BX Options, from \$0.12 to \$0.13 per contract is equitable and not unfairly discriminatory because the Exchange would assess the same Fixed Fee that is proposed when routing Customer orders to a NASDAQ OMX exchange. All market participants that route an order to an away market, other than NOM or BX Options, would be assessed a uniform fee of \$0.13 per contract if the away market (non-NASDAQ OMX exchange) pays a rebate. These proposals would apply uniformly to all market participants when routing to an away market that pays a rebate, other than NOM and BX Options.

In addition, market participants may submit orders to the Exchange as ineligible for routing or "DNR" to avoid Routing Fees.¹⁵ Also, orders are routed to an away market based on price first.¹⁶

Finally, the Exchange believes that the added aggregation language regarding members and member organizations under Common Ownership is reasonable because the Exchange desires to attract liquidity. The added language is equitable and not unfairly discriminatory because it would apply to all members and member organizations uniformly. The Customer Rebate requirements regarding Tier and volume remain in place. However, all members and member organizations that are under Common Ownership will have the ability to aggregate their Customer volume for the purpose of calculating discount thresholds and receiving discounted routing fees. The Exchange will apply the aggregation language to all members and member organizations in a uniform manner.

¹³ See Rule 1080(m).

¹⁴ See Phlx Rule 1080(m)(iii)(A). See also Chapter VI, Section 11 of BX Options Rules and NOM Rules.

¹⁵ See Rule 1080(m)(iv).

¹⁶ See Rule 1080(m). See also Chapter VI, Section 11 of the BX Options Rules and NOM Rules.

The proposal allows the Exchange to continue attracting liquidity to Phlx while recouping costs incurred by the Exchange to route orders to away markets.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposal creates a burden on intra-market competition because the Exchange is applying the same Routing Fees to all market participants in the same manner dependent on the routing venue, with the exception of Customers. The Exchange will continue to assess separate Customer Routing Fees. Customers will continue to receive the lowest fees as compared to non-Customers when routing orders, as is the case today. Other options exchanges also assess lower Routing Fees for customer orders as compared to non-customer orders.¹⁷

The Exchange's proposal would allow the Exchange to continue to recoup its costs when routing Customer orders to NOM or BX Options as well as away markets that pay a rebate when such orders are designated as available for routing by the market participant. The Exchange continues to pass along savings realized by leveraging NASDAQ OMX's infrastructure and scale to market participants when Customer orders are routed to NOM and BX Options and is providing those savings to all market participants. Today, other options exchanges also assess fixed routing fees to recoup costs incurred by the exchange to route orders to away markets.¹⁸ Market participants may submit orders to the Exchange as ineligible for routing or "DNR" to avoid Routing Fees. It is important to note that when orders are routed to an away market they are routed based on price first. Today, other options exchanges also assess similar fees to recoup costs incurred when routing orders to away markets.

The Exchange is seeking to encourage market participants to transact a greater number of Customer orders on Phlx, which liquidity benefits all market participants. Customer liquidity benefits

all market participants by providing more trading opportunities, which attracts specialists and other market makers. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants. In addition, the credit toward Customer Routing Fees is in addition to the Customer rebate received for the qualifying Customer Rebate Tier.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Pursuant to Section 19(b)(3)(A)(ii) of the Act,¹⁹ the Exchange has designated this proposal as establishing or changing a due, fee, or other charge imposed by the self-regulatory organization on any person, whether or not the person is a member of the self-regulatory organization, which renders the proposed rule change effective upon filing.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-Phlx-2014-68 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities

and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-Phlx-2014-68. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-Phlx-2014-68 and should be submitted on or before December 4, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁰

Kevin M. O'Neill,

Deputy Secretary.

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¹⁷ BATS assesses lower customer routing fees as compared to non-customer routing fees per the away market. For example BATS assesses ISE customer routing fees of \$0.52 per contract and an ISE non-customer routing fee of \$ 0.65 per contract. See BATS BZX Exchange Fee Schedule.

¹⁸ See CBOE's Fees Schedule and ISE's Fee Schedule.

¹⁹ 15 U.S.C. 78s(b)(3)(A)(ii).

²⁰ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-73554; File No. SR-NYSE-2014-56]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Its Rules Concerning Supervision To Harmonize the Rules With Certain Financial Industry Regulatory Authority, Inc. Rules and Making Other Conforming Changes

November 6, 2014.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 (the “Act”) and Rule 19b-4 thereunder,² notice is hereby given that on October 24, 2014, New York Stock Exchange LLC (“NYSE” or “Exchange”) filed with the Securities and Exchange Commission (“SEC” or “Commission”) the proposed rule change as described in Items I and II below, which Items have been substantially prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons. The Exchange has designated the proposed rule change as constituting a “non-controversial” rule change under Rule 19b-4(f)(6) of the Act,³ which renders the proposal effective upon receipt of this filing by the Commission.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend NYSE rules concerning supervision to harmonize the rules with certain Financial Industry Regulatory Authority, Inc. (“FINRA”) rules and make other conforming changes. The text of the proposed rule change is available on the Exchange's Web site at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The

Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its rules concerning supervision to harmonize the rules with certain FINRA rules and make other conforming changes. Set forth below are descriptions of the harmonization process, the current NYSE rules, and the proposed NYSE rules. Specifically, the Exchange proposes to: (1) Adopt new rule text that is substantially similar to FINRA Rules 3110, 3120, 3150, and 3170; (2) delete Rule 342 and related Rule Interpretations (except for certain text in Rule 342.13 and related Rule Interpretation regarding qualifications and exam requirements for individuals with supervisory responsibilities), Rule 351(e) and related Rule Interpretations, Rule 354, Rule 401, and Rule 401A; and (3) make other conforming changes.⁴

Background

On July 30, 2007, FINRA's predecessor, the National Association of Securities Dealers, Inc. (“NASD”), and NYSE Regulation, Inc. (“NYSER”) consolidated their member firm regulation operations into a combined organization, FINRA. Pursuant to Rule 17d-2 under the Act,⁵ the Exchange, NYSER, and FINRA entered into an agreement (“Agreement”) to reduce regulatory duplication for their members by allocating to FINRA certain regulatory responsibilities for NYSE rules and rule interpretations (“FINRA Incorporated NYSE Rules”). NYSE MKT LLC (“NYSE MKT”) became a party to the Agreement effective December 15, 2008.⁶

As part of its effort to reduce regulatory duplication and relieve firms that are members of FINRA, the Exchange, and NYSE MKT of conflicting or unnecessary regulatory burdens,

FINRA is now engaged in the process of reviewing and amending the NASD and FINRA Incorporated NYSE Rules in order to create a consolidated FINRA rulebook.⁷

FINRA recently harmonized NASD and FINRA Incorporated NYSE Rules and interpretations concerning supervision. More particularly, FINRA: (1) Adopted FINRA Rules 3110 and 3120 to largely replace NASD Rules 3010 and 3012, respectively; (2) incorporated into FINRA Rule 3110 and its supplementary material the requirements of NASD IM-1000-4, NASD IM-3010-1, FINRA Incorporated NYSE Rule 401A, and FINRA Incorporated NYSE Rule 342.21; (3) replaced NASD Rule 3010(b)(2) with new FINRA Rule 3170; (4) replaced NASD Rule 3110(i) with new FINRA Rule 3150; and (5) deleted the following FINRA Incorporated NYSE Rules and NYSE Rule Interpretations: (i) NYSE Rule 342 and related NYSE Rule Interpretations; (ii) NYSE Rule 343 and related NYSE Rule Interpretations; (iii) NYSE Rule 351(e) and related NYSE Rule Interpretation; (iv) NYSE Rule 354; (v) NYSE Rule 401; and (vi) NYSE Rule 401A.⁸

FINRA has announced that the effective date for the rule change will be December 1, 2014. The Exchange proposes to make its proposed rule change effective on the same date as FINRA, and will announce the effective date via an Information Memo.⁹

Current Supervision Rules and Interpretations

Rule 342(a) requires each office, department or business activity of a member or member organization (including foreign incorporated branch offices) to be under the supervision and control of the member or member

⁷ FINRA's rulebook currently has three sets of rules: (1) NASD Rules, (2) FINRA Incorporated NYSE Rules, and (3) consolidated FINRA Rules. The FINRA Incorporated NYSE Rules apply only to those members of FINRA that are also members of the NYSE (“Dual Members”), while the consolidated FINRA Rules apply to all FINRA members. For more information about the FINRA rulebook consolidation process, see FINRA Information Notice, dated March 12, 2008.

⁸ See Exchange Act Release No. 71179 (Dec. 23, 2013), 78 FR 79542 (Dec. 30, 2013) (SR-FINRA-2013-025).

⁹ There is one exception. Effective as of April 7, 2014, in order to coincide with related changes to Form BR, the Exchange deleted NYSE Rule 343 and the related interpretations and FINRA deleted the related FINRA Incorporated NYSE Rule and NYSE Rule Interpretations. See FINRA Regulatory Notices 14-10 and 14-11 and Exchange Act Release No. 71989 (Apr. 22, 2014), 79 FR 23391 (Apr. 28, 2014) (SR-NYSE-2014-21). See also Exchange Act Release No. 73325 (Oct. 9, 2014), 79 FR 61360 (Oct. 10, 2014) (SR-NYSE-2014-55) (conforming amendments related to the deletion of NYSE Rule 343).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 17 CFR 240.19b-4(f)(6).

⁴ References to rules are to NYSE rules unless otherwise indicated.

⁵ 17 CFR 240.17d-2.

⁶ See Exchange Act Release Nos. 56148 (Jul. 26, 2007), 72 FR 42146 (Aug. 1, 2007) (order approving the Agreement); 56147 (Jul. 26, 2007), 72 FR 42166 (Aug. 1, 2007) (SR-NASD-2007-054) (order approving the incorporation of certain NYSE Rules as “Common Rules”); 60409 (Jul. 30, 2009), 74 FR 39353 (Aug. 6, 2009) (order approving the amended and restated Agreement, adding NYSE MKT LLC as a party). Paragraph 2(b) of the Agreement sets forth procedures regarding proposed changes by FINRA, NYSE or NYSE MKT to the substance of any of the Common Rules.

organization establishing it and of the personnel delegated such authority and responsibility. The person in charge of a group of employees must reasonably discharge his duties and obligations in connection with supervision and control of the activities of those employees related to the business of their employer and compliance with securities laws and regulations.

Rule 342(b) provides that the general partners or directors of each member organization must provide for appropriate supervisory control and must designate a general partner or principal executive to assume overall authority and responsibility for internal supervision and control of the organization and compliance with securities' laws and regulations. This person must:

- Delegate to qualified principals or employees responsibility and authority for supervision and control of each office, department or business activity, and provide for appropriate procedures of supervision and control; and
- Establish a separate system of follow-up and review to determine that the delegated authority and responsibility is being properly exercised.

Rule 342(c) provides that a member organization must provide notice to the Exchange of each branch office established by such member organization.

Rule 342(d) provides that qualified persons acceptable to the Exchange must be in charge of:

- Any office of a member or member organization;
- Any regional or other group of offices; and
- Any sales department or activity.

Rule 342(e) provides that the amounts and types of credit extended by a member organization must be supervised by members or principal executives qualified by experience for such control in the types of business in which the member organization extends credit.

Supplementary Materials 342.10-.30 provide additional guidance relating to the definition of branch offices, annual fees, foreign branch offices, the acceptability of supervisors, the experience of senior management, small offices, the supervision of registered representatives, the review of communications with the public, bookkeeping, the supervision of producing managers, information requests, trade review and investigation, the definition of related financial instrument, internal controls, annual branch office inspection, risk-based surveillance and branch office

identification, criteria for inspection programs, and annual reports and certifications. The related Rule 342 Interpretations provide further guidance relating to the foregoing.

Rule 351(e) provides that each member not associated with a member organization and a principal executive of each member organization must take one or both of the following two actions in relation to the trades that are subject to the review procedures required by Rule 342.21(a):

- Sign a written statement in the form specified in the rule and deliver it to the Exchange by the 15th day of the month following the calendar quarter in which the trade occurred.

- As to any such trade that is the subject of an internal investigation pursuant to Rule 342.21(b), but has not been both resolved and included in the written statement, report in writing to the Exchange:

- The commencement of the internal investigation, the identity of the trade, and the reason why the trade could not be the subject of the written statement (report by the 15th day of the month, following the calendar quarter in which the trade occurred);

- the quarterly progress of each open investigation (report by the 15th day of the month following the quarter); and
- the completion of the investigation, detailing the methodology and results of the investigation, any internal disciplinary action taken, and any referral of the matter to the Exchange, another self-regulatory organization ("SRO"), the Commission or another Federal agency, and including, where no internal disciplinary action has been taken and no such referral has been made, a written statement in relation to the trade in the form specified below (report within one week after completion of the investigation).

Rule 351(e) also provides that when a statement pertains to one or more trades that have been the subject of an internal investigation pursuant to Rule 342.21(b) but as to which no internal disciplinary action has been taken and no referral of the matter to the Exchange, another SRO, or a Federal agency has been made, the written statement must also refer to the particular trade(s) (rather than to the trades of a particular calendar quarter) and must omit the clause excepting trades reported as the subject of an investigation. The related Rule 351 Interpretations provide additional guidance relating to the foregoing.

Rule 354(a) provides that, by April 1 of each year, each member organization must submit a copy of its Rule 342.30 annual report on supervision and

compliance to its control person(s) or, if the member organization has no control person, to the audit committee of its Board of Directors or its equivalent committee or group. In the case of a control person that is an organization (a "controlling organization"), the member organization must submit the report to the general counsel of the controlling organization and to the audit committee of the controlling organization's Board of Directors or its equivalent committee or group.

Rule 354(b) provides that, for the purpose of Rule 354(a), "control person" means a person who controls the member organization within the meaning of Rule 2 otherwise than solely by virtue of being a director, general partner, or principal executive (or person occupying a similar status or performing similar functions) of the member organization.

Rule 401(b) provides that each member and member organization must maintain written policies and procedures, administered pursuant to the internal control requirements prescribed under Rule 342.23, specifically with respect to the following activities:

- Transmittals of funds (e.g., wires, checks, etc.) or securities;
- From customer accounts to third party accounts (i.e., a transmittal that would result in a change of beneficial ownership);
- from customer accounts to outside entities (e.g., banks, investment companies, etc.);
- from customer accounts to locations other than a customer's primary residence (e.g., post office box, "in care of" accounts, alternate address, etc.); and
- between customers and registered representatives (including the hand-delivery of checks).
- Customer changes of address.
- Customer changes of investment objectives.

The policies and procedures required under Rule 401(b)(1), (2), and (3) must include a means/method of customer confirmation, notification, or follow-up that can be documented.

Rule 401A(a) provides that, for every customer complaint they receive that is subject to the reporting requirements of Rule 4530(d), members and member organizations must:

- Acknowledge receipt of the complaint within 15 business days of receiving it; and
- Respond to the issues raised in the complaint within a reasonable period of time.

Rule 401A(b) provides that each acknowledgement and response

required by this rule must be conveyed to the complaining customer by an appropriate method. More specifically:

- Acknowledgements and responses to written complaints must be either:
 - In writing, mailed to the complaining customer's last known address; or
 - Electronically transmitted to the email address from which the complaint was sent (method only permissible for electronically transmitted complaints).
- Acknowledgements and responses to verbal complaints must be either:
 - In writing, mailed to the complaining customer's last known address; or
 - Made verbally to the complaining customer, and recorded in a log of verbal acknowledgements and responses to customer complaints.

Rule 401A(c) provides that written records of the acknowledgements, responses, and logs required by this rule must be retained in accordance with Rule 440.

Proposed Rule Change

The Exchange proposes to delete the foregoing rules and interpretations relating to supervision (except as noted below), which are, in main part, either duplicative of, or do not align with, the proposed supervision requirements discussed below, and adopt the text of FINRA Rules 3110, 3120, 3150, and 3170, subject to certain technical and conforming changes.¹⁰ As noted in Rule 0, NYSE rules that refer to NYSE, NYSE staff or departments, Exchange staff, and Exchange departments should be understood as also referring to FINRA staff and FINRA departments acting on behalf of the Exchange pursuant to the Agreement, as applicable.

The Exchange proposes to retain the requirements contained in Rule 342.13(a) and (b) and related interpretations regarding qualifications and exam requirements for individuals with supervisory responsibilities. The proposed new version of Rule 342(a), corresponding to current Rule 342.13(a), would provide that any member or employee identified as in charge of (1) any office of a member or member organization, (2) any regional or other group of offices, or (3) any sales department or activity must have a

creditable record and pass the General Securities Sales Supervisor Qualification Examination (Series 9/10) or another examination acceptable to the Exchange. The proposed new version of Rule 342(a) would retain the current requirement in the Interpretation to Rule 342 that every branch office or sales manager must have at least three years' experience as a registered representative or substantial experience in a related sales or managerial position and must pass the Series 9/10.

Further, the proposed new version of Rule 342(a) would retain the current examples of a related sales or managerial position in the Interpretation to Rule 342 and the requirement that in order to qualify as a supervisory person, a principal executive¹¹ should have at least three years' experience as a registered representative unless granted an exception. The proposed new version of Rule 342(a) would also retain from the related Interpretation that the General Securities Principal Examination (Series 24) is an acceptable alternative for persons whose duties do not include the supervision of options or municipal securities sales activity and that the examination requirement may be waived at the discretion of the Exchange. Finally, the proposed new version of Rule 342(a) would retain the requirement from the Interpretation that in the case of a firm applying for registered broker-dealer status, the supervisory candidates must have at least one year of direct experience or two years of related experience in the subject area to be supervised in addition to the requirements outlined above.

The proposed new version of Rule 342(b), corresponding to current Rule 342.13(b), would provide that the individuals designated as having day-to-day compliance responsibilities for their respective firms, or who supervise ten or more persons engaged in compliance activities, have the knowledge necessary to carry out their job responsibilities (*i.e.*, overall knowledge of the securities laws and Exchange rules) and pass the Compliance Official Examination (the "Series 14") or, in the case of compliance supervisors of member organizations that conduct a Designated Market Maker ("DMM") business, the DMM Compliance Official Examination (the "Series 14A"). The proposed new version of Rule 342(b) would also retain the current requirement in the

Interpretation to Rule 342 that member organizations engaged in a public business in addition to a DMM business must have a qualified compliance supervisor who has passed both the Series 14 and Series 14A Examinations. Finally, the proposed new version of Rule 342(b) would incorporate the following exemptions from the Series 14 Examination requirement (currently contained in the Interpretation to Rule 342):

- Compliance supervisors at member organizations whose activities are solely related to execution of orders on the Exchange trading floor and who do not conduct any business with the public;
- Compliance supervisors at member organizations whose commissions and other fees from public business (retail and institutional) are under \$500,000 in the preceding calendar year and who introduce to another broker-dealer; and
- Supervisors of ten or more persons whose compliance responsibilities are limited to the registration of member organization employees with the various regulators and SROs.

Proposed Rule 3110 (Supervision)

Proposed Rule 3110 is based primarily on requirements in the FINRA rulebook and current Rule 342 relating to, among other things, supervisory systems, written procedures, internal inspections, and review of correspondence.

Proposed Rule 3110(a)

Proposed Rule 3110(a) would cover supervisory systems and would require each member organization to establish and maintain a system to supervise the activities of each associated person that is reasonably designed to achieve compliance with applicable securities laws and regulations, and with applicable Exchange rules. Under the proposed rule, final responsibility for proper supervision would rest with the member organization. In addition, a member organization's supervisory system would be required to provide, at a minimum, for the following:

- The establishment and maintenance of written procedures as required by proposed Rule 3110.
- The designation, where applicable, of an appropriately registered principal with authority to carry out the supervisory responsibilities of the member organization for each type of business in which it engages for which registration as a broker-dealer is required.

• The registration and designation as a branch office or an office of supervisory jurisdiction ("OSJ") of each location, including the main office, that

¹⁰ The technical and conforming changes are that the Exchange would: (1) substitute the term "member organization" for "member," (2) substitute the term "Exchange" for "FINRA," (3) change certain cross-references to FINRA rules to cross-references to Exchange rules, and (4) add supplementary material to define the term "associated person" in proposed Rules 3110, 3120, and 3150.

¹¹ The Interpretation to Rule 342 refers to "allied members," a category the Exchange eliminated and replaced with "principal executive," which has substantially the same meaning. See Exchange Act Release No. 58549 (Sept. 15, 2008), 73 FR 54444 (Sept. 19, 2008) (SR-NYSE-2008-80).

meets the definitions contained in proposed Rule 3110(e).¹²

- The designation of one or more appropriately registered principals in each OSJ and one or more appropriately registered representatives or principals in each non-OSJ branch office with authority to carry out the supervisory responsibilities assigned to that office by the member organization.
- The assignment of each registered person to an appropriately registered representative or principal who would be responsible for supervising that person's activities.
- The use of reasonable efforts to determine that all supervisory personnel are qualified, either by virtue of experience or training, to carry out their assigned responsibilities.
- The participation of each registered representative and registered principal, either individually or collectively, no less than annually, in an interview or meeting conducted by persons designated by the member organization at which compliance matters relevant to the activities of the representative and principal are discussed, which may occur in conjunction with the discussion of other matters and may be conducted at a central or regional location or at the representative's or principal's place of business.

Proposed Rule 3110(b)

In proposed Rule 3110(b), the Exchange proposes to consolidate provisions from current Rule 401A relating to the review of customer complaints with various provisions and rules from the FINRA rulebook that currently require written procedures, including provisions relating to the supervision and review of registered representatives' transactions and correspondence. In addition, proposed supplementary material, which is discussed in detail below, would codify and expand guidance in these areas.

Proposed Rule 3110(b)(1) would address written procedures and would require each member organization to establish, maintain, and enforce written procedures to supervise the types of business in which it engages and the activities of its associated persons that are reasonably designed to achieve compliance with applicable securities laws and regulations and applicable Exchange rules.

Under proposed Rule 3110(b)(2), the supervisory procedures required by

proposed Rule 3110(b) would include procedures for the review by a registered principal, evidenced in writing, of all transactions relating to the investment banking or securities business of the member organization.

Consistent with FINRA Rule 3110(b)(3), proposed Rule 3110(b)(3) would be marked "Reserved."

Under proposed Rule 3110(b)(4), the supervisory procedures required by proposed Rule 3110(b) would also include procedures for the review of incoming and outgoing written (including electronic) correspondence and internal communications relating to the member organization's investment banking or securities business and be appropriate for the member organization's business, size, structure, and customers. The supervisory procedures would require the member organization's review of:

- Incoming and outgoing written (including electronic) correspondence to properly identify and handle in accordance with firm procedures, customer complaints, instructions, funds and securities, and communications that are of a subject matter that require review under Exchange rules and federal securities laws; and
- Internal communications to properly identify those communications that are of a subject matter that require review under Exchange rules and federal securities laws.

Such reviews would be conducted by a registered principal and would be evidenced in writing, either electronically or on paper. Those communications subject to review would include (without limitation):

- Communications between non-research and research departments concerning a research report's contents (Rule 472(b)(3)).
- Certain communications with the public that require a principal's pre-approval (Rule 2210).
- The identification and reporting to the Exchange of customer complaints (Rule 4530).¹³

Current Rule 401A requires firms to acknowledge and respond to all customer complaints subject to the reporting requirements of current Rule 4530(d). Previously, this meant that firms had to acknowledge and respond to both written and oral customer complaints. However, as part of the effort to harmonize the NASD and NYSE

rules in the interim period before completion of the Consolidated FINRA Rulebook, current Rule 4530(d) was amended to limit the definition of "customer complaint" to include only written complaints, thereby making the definition substantially similar to that in FINRA Rule 4530(d).¹⁴

Proposed Rule 3110(b)(5), which requires a member organization's supervisory procedures to include procedures to capture, acknowledge, and respond to all written (including electronic) customer complaints, essentially incorporates the customer complaint requirement in current Rule 401A, including the limitation on including only written (including electronic) customer complaints. The Exchange believes that oral complaints are difficult to capture and assess, and that they raise competing views as to the substance of the complaint being alleged. Consequently, the Exchange believes that oral complaints do not lend themselves as effectively to a review program as written complaints, which are more readily documented and retained. However, the Exchange reminds member organizations that the failure to address any customer complaint, written or oral, may be a violation of Rule 2010.

Under proposed Rule 3110(b)(6), the supervisory procedures required by proposed Rule 3110(b) must set forth the supervisory system established by the member organization pursuant to proposed Rule 3110(a), and would include:

- The titles, registration status, and locations of the required supervisory personnel and the responsibilities of each supervisory person as these relate to the types of business engaged in, applicable securities laws and regulations, and Exchange rules.
- A record, preserved by the member organization for a period of not less than three years, the first two years in an easily accessible place, of the names of all persons who are designated as supervisory personnel and the dates for which such designation is or was effective.
- Procedures prohibiting associated persons who perform a supervisory function from:
 - Supervising their own activities; and
 - Reporting to, or having their compensation or continued employment determined by, a person or persons they are supervising.

¹² Although to date the Exchange and FINRA have used the same definition for "branch office," the Exchange has not previously designated OSJs. As such, the requirements relating to OSJs described hereinafter would be new for member organizations.

¹³ With respect to customer complaints, proposed Rule 3110(b)(5) also would affirmatively require members to capture, acknowledge, and respond to all written (including electronic) customer complaints.

¹⁴ The Exchange adopted the text of FINRA Rule 4530 to replace comparable provisions in Rule 351. See Exchange Act Release No. 64785 (Jun. 30, 2011), 76 FR 39946 (Jul. 7, 2011) (SR-NYSE-2011-27).

- If a member organization determines, with respect to any of its supervisory personnel, that compliance with the preceding two bullets is not possible because of the member organization's size or a supervisory personnel's position within the firm, the member organization would be required to document:

- The factors the member organization used to reach such determination; and
- How the supervisory arrangement with respect to such supervisory personnel otherwise complies with proposed Rule 3110(a).
- Procedures reasonably designed to prevent the supervisory system required pursuant to proposed Rule 3110(a) from being compromised due to the conflicts of interest that may be present with respect to the associated person being supervised, including the position of such person, the revenue such person generates for the firm, or any compensation that the associated person conducting the supervision may derive from the associated person being supervised.

Proposed Rule 3110(b)(7) would require a member organization to keep and maintain a copy of its written supervisory procedures, or such relevant portions, in each OSJ and at each location where supervisory activities are conducted on behalf of the member organization. Each member organization would be required to promptly amend its written supervisory procedures to reflect changes in applicable securities laws or regulations, including Exchange rules, and as changes occur in its supervisory system. Each member organization would be responsible for promptly communicating its written supervisory procedures and amendments to all associated persons to whom such written supervisory procedures and amendments are relevant based on their activities and responsibilities.

Proposed Rule 3110(c)

Proposed Rule 3110(c) would cover internal inspections. Proposed Rule 3110(c)(1) would require each member organization to conduct a review, at least annually (on a calendar-year basis), of the businesses in which it engages. The review must be reasonably designed to assist the member organization in detecting and preventing violations of, and achieving compliance with, applicable securities laws and regulations, and with applicable Exchange rules. Each member organization would be required to review the activities of each office, which would include the periodic

examination of customer accounts to detect and prevent irregularities or abuses. Each member organization would also be required to retain a written record of the date upon which each review and inspection is conducted.

In addition, proposed Rule 3110(c)(1) would require each member organization to inspect at least annually (on a calendar-year basis) every OSJ and any branch office that supervises one or more non-branch locations. Each member organization would also be required to inspect at least every three years every branch office that does not supervise one or more non-branch locations. In establishing how often to inspect each non-supervisory branch office, the member organization would be required to consider whether the nature and complexity of the securities activities for which the location is responsible, the volume of business done at the location, and the number of associated persons assigned to the location require the non-supervisory branch office to be inspected more frequently than every three years. If a member organization establishes a more frequent inspection cycle, the member organization would be required to ensure that at least every three years, the inspection requirements enumerated in proposed Rule 3110(c)(2) have been met. The member organization's written supervisory and inspection procedures would have to set forth the non-supervisory branch office examination cycle, an explanation of the factors the member organization used in determining the frequency of the examinations in the cycle, and the manner in which a member organization would comply with proposed Rule 3110(c)(2) if using more frequent inspections than every three years.

Under proposed Rule 3110(c)(1), each member organization would also be required to inspect every non-branch location on a regular, periodic schedule. In establishing such a schedule, the member organization would be required to consider the nature and complexity of the securities activities for which the location is responsible and the nature and extent of contact with customers. The member organization's written supervisory and inspection procedures would have to set forth the schedule and an explanation regarding how the member organization determined the frequency of the examination.

Proposed Rule 3110(c)(2) would require that the inspection and review by a member organization pursuant to proposed Rule 3110(c)(1) be reduced to a written report and kept on file by the member organization for a minimum of

three years, unless the inspection is being conducted pursuant to proposed Rule 3110(c)(1)(C) and the regular periodic schedule is longer than a three-year cycle, in which case the report would have to be kept on file at least until the next inspection report has been written. If applicable to the location being inspected, proposed Rule 3110(c)(2)(A) would require that location's written inspection report to include, without limitation, the testing and verification of the member organization's policies and procedures, including supervisory policies and procedures in the following areas:

- Safeguarding of customer funds and securities;
- Maintaining books and records;
- Supervision of supervisory personnel;
- Transmittals of funds (e.g., wires or checks, etc.) or securities from customers to third party accounts; from customer accounts to outside entities (e.g., banks, investment companies, etc.); from customer accounts to locations other than a customer's primary residence (e.g., post office box, "in care of" accounts, alternate address, etc.); and between customers and registered representatives, including the hand-delivery of checks; and
- Changes of customer account information, including address and investment objectives changes and validation of such changes.

Under proposed Rules 3110(c)(2)(B) and 3110(c)(2)(C), a member organization's policies and procedures regarding transmittals of funds must include a means or method of customer confirmation, notification, or follow-up that can be documented. Member organizations could use reasonable risk-based criteria to determine the authenticity of the transmittal instructions. The policies and procedures regarding changes in customer account information would have to include, for each change processed, a means or method of customer confirmation, notification, or follow-up that can be documented and that complies with Rules 17a-3(a)(17)(i)(B)(2) and 17a-3(a)(17)(i)(B)(3) under the Act.¹⁵

Pursuant to proposed Rule 3110(c)(2)(D), if a member organization does not engage in all of the activities enumerated in the bullets immediately above at the location being inspected, the member organization would be required to identify those activities in the member organization's written supervisory procedures or the location's

¹⁵ 17 CFR 240.17a-3(a)(17)(i)(B)(2) and 17 CFR 240.17a-3(a)(17)(i)(B)(3).

written inspection report and document in the member organization's written supervisory procedures or the location's written inspection report that supervisory policies and procedures for such activities must be in place at that location before the member organization can engage in them.

Under proposed Rule 3110(c)(3), for each inspection conducted pursuant to the proposed rule, a member organization would be required to:

- Have procedures reasonably designed to prevent the effectiveness of inspections from being compromised due to conflicts of interest that may be present with respect to the location being inspected, including but not limited to, economic, commercial, or financial interests in the associated persons and businesses being inspected; and

- Ensure that the person conducting an inspection is not an associated person assigned to the location or is not directly or indirectly supervised by, or otherwise reporting to, an associated person assigned to the location.

Under the proposed rule, if a member organization determines that compliance with these two bullets is not possible either because of a member organization's size or its business model, the member organization would be required to document in the inspection report both the factors the member organization used to make its determination and how the inspection otherwise complies with proposed Rule 3110(c)(1).

By way of comparison, under current Rules 342.24 and 342.25, each branch office must be inspected annually, unless the member organization obtained an exemption by submitting to the Exchange written policies and procedures for systematic risk-based surveillance of its branch offices, in which case each branch office must be inspected at least every three years. The proposed subject matter requirements for inspection reports are substantially the same as the current subject matter requirements.

Proposed Rule 3110(d)

Section 15(g) of the Act, adopted as part of the Insider Trading and Securities Fraud Enforcement Act of 1988,¹⁶ requires every registered broker or dealer to establish, maintain, and enforce written policies and procedures reasonably designed to prevent the misuse of material, non-public information by the broker or dealer or

any associated person of the broker or dealer.¹⁷ Current Rule 342.21 sets forth specific supervisory procedures for compliance with Section 15(g) by requiring firms to review trades in Exchange-listed securities and related financial instruments that are effected for the member organization's account or for the accounts of the member organization's employees and family members. Current Rule 342.21 also requires member organizations to promptly conduct an internal investigation into any trade the firm identifies that may have violated insider trading laws or rules.

Proposed Rule 3110(d) incorporates provisions of current Rule 342.21, with some modifications, and extends the requirement beyond Exchange-listed securities and related financial instruments to cover all securities. Proposed Rule 3110(d) would cover transaction reviews and investigations. Proposed Rule 3110(d)(1) would require each member organization to include in its supervisory procedures a process for the review of securities transactions reasonably designed to identify trades that may violate the provisions of the Act, the rules thereunder, or Exchange rules prohibiting insider trading and manipulative and deceptive devices that are effected for the:

- Accounts of the member organization;
- Accounts introduced or carried by the member organization in which a person associated with the member organization has a beneficial interest or the authority to make investment decisions;
- Accounts of a person associated with the member organization that are disclosed to the member organization pursuant to Rule 407 or NASD Rule 3050, as applicable; and
- Covered accounts.

Under proposed Rule 3110(d)(2), each member organization would be required to promptly conduct an internal investigation into any such trade to determine whether a violation of those laws or rules has occurred. In addition, under proposed Rule 3110(d)(3), a member organization engaging in investment banking services would be required to file written reports with the Exchange, signed by a senior officer of the member organization, at such times and, without limitation, including such content, as follows:

- Within ten business days of the end of each calendar quarter, a written report describing each internal investigation initiated in the previous calendar quarter pursuant to proposed

Rule 3110(d)(2), including the identity of the member organization, the date each internal investigation commenced, the status of each open internal investigation, the resolution of any internal investigation reached during the previous calendar quarter, and, with respect to each internal investigation, the identity of the security, trades, accounts, associated persons of the member organization, or associated person of the member organization's family members holding a covered account, under review, and that includes a copy of the member organization's policies and procedures required by proposed Rule 3110(d)(1).

- Within five business days of completion of an internal investigation pursuant to proposed Rule 3110(d)(2) in which it was determined that a violation of the provisions of the Act, the rules thereunder, or Exchange rules prohibiting insider trading and manipulative and deceptive devices had occurred, a written report detailing the completion of the investigation, including the results of the investigation, any internal disciplinary action taken, and any referral of the matter to the Exchange, another SRO, the SEC, or any other federal, state, or international regulatory authority.

For purposes of proposed Rule 3110(d)(4), the following definitions would apply:

- The term "covered account" would include any account introduced or carried by the member organization that is held by:

- The spouse of a person associated with the member organization;
- A child of the person associated with the member organization or such person's spouse, provided that the child resides in the same household as, or is financially dependent upon, the person associated with the member organization;
- Any other related individual over whose account the person associated with the member organization has control; or
- Any other individual over whose account the associated person of the member organization has control and to whose financial support such person materially contributes.

- The term "investment banking services" would include, without limitation, acting as an underwriter, participating in a selling group in an offering for the issuer, or otherwise acting in furtherance of a public offering of the issuer; acting as a financial adviser in a merger or acquisition; providing venture capital or equity lines of credit or serving as placement agent for the issuer or otherwise acting in

¹⁶ See Insider Trading and Securities Fraud Enforcement Act of 1988, Public Law No. 100-704, 102 Stat. 4677.

¹⁷ 15 U.S.C. 78o(g).

furtherance of a private offering of the issuer.

Proposed Rule 3110(e)

Proposed Rule 3110(e) would define “OSJ” and “branch office.” As noted above, “OSJ” would be a new designation for the Exchange and the definition of the term would substantially mirror FINRA’s definition. The term “OSJ” would mean any office of a member organization at which any one or more of the following functions take place:

- Order execution or market making;
- Structuring of public offerings or private placements;
- Maintaining custody of customers’ funds or securities;
- Final acceptance (approval) of new accounts on behalf of the member organization;
- Review and endorsement of customer orders;
- Final approval of retail communications for use by persons associated with the member organization, pursuant to Rule 2210(b)(1), except for an office that solely conducts final approval of research reports; or
- Responsibility for supervising the activities of persons associated with the member organization at one or more other branch offices of the member organization.

The definition of “branch office” would be substantially the same as current Rule 342.10. It would mean any location where one or more associated persons of a member organization regularly conducts the business of effecting any transactions in, or inducing or attempting to induce the purchase or sale of, any security, or is held out as such, excluding:

- Any location that is established solely for customer service or back office type functions where no sales activities are conducted and that is not held out to the public as a branch office;
- Any location that is the associated person’s primary residence, provided that:
 - Only one associated person, or multiple associated persons who reside at that location and are members of the same immediate family, conduct business at the location;
 - The location is not held out to the public as an office and the associated person does not meet with customers at the location;
 - Neither customer funds nor securities are handled at that location;
 - The associated person is assigned to a designated branch office, and such designated branch office is reflected on all business cards, stationery, retail

communications and other communications to the public by such associated person;

- The associated person’s correspondence and communications with the public are subject to the firm’s supervision in accordance with proposed Rule 3110;

- Electronic communications (*e.g.*, email) are made through the member organization’s electronic system;

- All orders are entered through the designated branch office or an electronic system established by the member organization that is reviewable at the branch office;

- Written supervisory procedures pertaining to supervision of sales activities conducted at the residence are maintained by the member organization; and

- A list of the residence locations is maintained by the member organization.

- Any location, other than a primary residence, that is used for securities business for less than 30 business days¹⁸ in any one calendar year, provided the member organization complies with the first eight of the nine immediately preceding bullet points;

- Any office of convenience, where associated persons occasionally and exclusively by appointment meet with customers, which is not held out to the public as an office;¹⁹

- Any location that is used primarily to engage in non-securities activities and from which the associated person(s) effects no more than 25 securities transactions in any one calendar year; provided that any retail communication identifying such location also sets forth the address and telephone number of the location from which the associated person(s) conducting business at the non-branch locations are directly supervised;

- The floor of a registered national securities exchange where a member organization conducts a direct access business with public customers; or

- A temporary location established in response to the implementation of a business continuity plan.

Notwithstanding the exclusions for branch offices described above, any location that is responsible for

¹⁸ The term “business day” would not include any partial business day provided that the associated person spends at least four hours on such business day at his or her designated branch office during the hours that such office is normally open for business.

¹⁹ Where such office of convenience is located on bank premises, signage necessary to comply with applicable federal and state laws, rules and regulations and applicable rules and regulations of other SROs, and securities and banking regulators could be displayed and would not be deemed “holding out” for purposes of this section.

supervising the activities of persons associated with the member organization at one or more non-branch locations of the member organization would be considered a branch office.

Proposed Supplementary Materials to Proposed Rule 3110

Proposed Supplementary Material .01 to Rule 3110 would require a member organization’s main office location to be registered and designated as a branch office or OSJ if it meets the definitions of a “branch office” or “office of supervisory jurisdiction” as set forth in proposed Rule 3110(e). In general, the nature of activities conducted at a main office will satisfy the requirements of such terms.

Proposed Supplementary Material .02 to Rule 3110 would provide that, in addition to the locations that meet the definition of OSJ in proposed Rule 3110(e), each member organization must also register and designate other offices as OSJs as is necessary to supervise its associated persons in accordance with the standards set forth in proposed Rule 3110. In making a determination as to whether to designate a location as an OSJ, the member organization should consider the following factors:

- Whether registered persons at the location engage in retail sales or other activities involving regular contact with public customers;
- Whether a substantial number of registered persons conduct securities activities at, or are otherwise supervised from, such location;
- Whether the location is geographically distant from another OSJ of the firm;
- Whether the member organization’s registered persons are geographically dispersed; and
- Whether the securities activities at such location are diverse or complex.

Proposed Supplementary Material .03 to Rule 3110 would provide additional guidance relating to proposed Rule 3110(a)(4), which would require a member organization to designate one or more appropriately registered principals in each OSJ with the authority to carry out the supervisory responsibilities assigned to that office (“on-site principal”). The proposed Supplementary Material would provide that the designated on-site principal for each OSJ must have a physical presence, on a regular and routine basis, at each OSJ for which the principal has supervisory responsibilities.

Consequently, there is a general presumption that a principal will not be designated and assigned to be the on-site principal pursuant to proposed Rule 3110(a)(4) to supervise more than one

OSJ. If a member organization determines it is necessary to designate and assign one appropriately registered principal to be the on-site principal pursuant to proposed Rule 3110(a)(4) to supervise two or more OSJs, the member organization must take into consideration, among others, the following factors:

- Whether the on-site principal is qualified by virtue of experience and training to supervise the activities and associated persons in each location;
- Whether the on-site principal has the capacity and time to supervise the activities and associated persons in each location;
- Whether the on-site principal is a producing registered representative;
- Whether the OSJ locations are in sufficiently close proximity to ensure that the on-site principal is physically present at each location on a regular and routine basis; and
- The nature of activities at each location, including size and number of associated persons, scope of business activities, nature and complexity of the products and services offered, volume of business done, the disciplinary history of persons assigned to such locations, and any other indicators of irregularities or misconduct.

The proposed Supplementary Material would provide that a member organization must establish, maintain, and enforce written supervisory procedures regarding the supervision of all OSJs. In all cases where a member organization designates and assigns one on-site principal to supervise more than one OSJ, the member organization must document in the member organization's written supervisory and inspection procedures the factors used to determine why the member organization considers such supervisory structure to be reasonable and the determination by the member organization will be subject to scrutiny.

Proposed Supplementary Material .04 to Rule 3110 would provide that a member organization is not required to conduct in-person meetings with each registered person or group of registered persons to comply with the annual compliance meeting (or interview) required by proposed Rule 3110(a)(7). A member organization that chooses to conduct compliance meetings using other methods (e.g., on-demand webcast or course, video conference, interactive classroom setting, telephone, or other electronic means) must ensure, at a minimum, that each registered person attends the entire meeting (e.g., an on-demand annual compliance webcast would require each registered person to use a unique user ID and password to

gain access and use a technology platform to track the time spent on the webcast, provide click-as-you-go confirmation, and have an attestation of completion at the end of a webcast) and is able to ask questions regarding the presentation and receive answers in a timely fashion (e.g., an on-demand annual compliance webcast that allows registered persons to ask questions via an email to a presenter or a centralized address or via a telephone hotline and receive timely responses directly or view such responses on the member organization's intranet site).

Proposed Supplementary Material .05 to Rule 3110 would provide that a member organization may use a risk-based review system to comply with proposed Rule 3110(b)(2)'s requirement that a registered principal review all transactions relating to the investment banking or securities business of the member organization. A member organization would not be required to conduct detailed reviews of each transaction if it is using a reasonably designed risk-based review system that provides it with sufficient information to permit it to focus on the areas that pose the greatest numbers and risks of violation.

Proposed Supplementary Material .06 to Rule 3110 would provide that, by employing risk-based principles, a member organization must decide the extent to which additional policies and procedures for the review of:

- Incoming and outgoing written (including electronic) correspondence that fall outside of the subject matters listed in proposed Rule 3110(b)(4) are necessary for its business and structure. If a member organization's procedures do not require that all correspondence be reviewed before use or distribution, the procedures must provide for:
 - The education and training of associated persons regarding the firm's procedures governing correspondence;
 - The documentation of such education and training; and
 - Surveillance and follow-up to ensure that such procedures are implemented and followed.
- Internal communications that are not of a subject matter that require review under Exchange rules and federal securities laws are necessary for its business and structure.

Proposed Supplementary Material .07 to Rule 3110 would provide that the evidence of review required in proposed Rule 3110(b)(4) must be chronicled either electronically or on paper and must clearly identify the reviewer, the internal communication or correspondence that was reviewed, the date of review, and the actions taken by

the member organization as a result of any significant regulatory issues identified during the review. Merely opening a communication would not be sufficient review.

Proposed Supplementary Material .08 to Rule 3110 would provide that, in the course of the supervision and review of correspondence and internal communications required by proposed Rule 3110(b)(4), a supervisor/principal may delegate certain functions to persons who need not be registered. However, the supervisor/principal would remain ultimately responsible for the performance of all necessary supervisory reviews, irrespective of whether he or she delegates functions related to the review. Accordingly, supervisors/principals must take reasonable and appropriate action to ensure delegated functions are properly executed and should evidence performance of their procedures sufficiently to demonstrate overall supervisory control.

Proposed Supplementary Material .09 to Rule 3110 would provide that each member organization must retain the internal communications and correspondence of associated persons relating to the member organization's investment banking or securities business for the period of time and accessibility specified in Rule 17a-4(b) under the Act. The names of the persons who prepared outgoing correspondence and who reviewed the correspondence must be ascertainable from the retained records, and the retained records must be readily available to the Exchange, upon request.

Proposed Supplementary Material .10 to Rule 3110 would provide that a member organization's determination that it is not possible to comply with proposed Rules 3110(b)(6)(C)(i) or (b)(6)(C)(ii) prohibiting supervisory personnel from supervising their own activities and from reporting to, or otherwise having compensation or continued employment determined by, a person or persons they are supervising generally will arise in instances where:

- The member organization is a sole proprietor in a single-person firm;
- A registered person is the member organization's most senior executive officer (or similar position); or
- A registered person is one of several of the member organization's most senior executive officers (or similar positions).

Proposed Supplementary Material .11 to Rule 3110 would provide that a member organization may use electronic media to satisfy its obligation to communicate its written supervisory procedures, and any amendment

thereto, pursuant to proposed Rule 3110(b)(7), provided that:

- The written supervisory procedures have been promptly communicated to, and are readily accessible by, all associated persons to whom such supervisory procedures apply based on their activities and responsibilities through, for example, the member organization's intranet system;

- All amendments to the written supervisory procedures are promptly posted to the member organization's electronic media;

- Associated persons are notified that amendments relevant to their activities and responsibilities have been made to the written supervisory procedures;

- The member organization has reasonable procedures to monitor and maintain the security of the material posted to ensure that it cannot be altered by unauthorized persons; and

- The member organization retains current and prior versions of its written supervisory procedures in compliance with the applicable record retention requirements of Rule 17a-4(e)(7) under the Act.

Proposed Supplementary Material .12 to Rule 3110 would provide that, in fulfilling its obligations under proposed Rule 3110(c), each member organization must conduct a review, at least annually, of the businesses in which it engages. The review must be reasonably designed to assist in detecting and preventing violations of and achieving compliance with applicable securities laws and regulations and with Exchange rules. Each member organization must establish and maintain supervisory procedures that must take into consideration, among other things, the firm's size, organizational structure, scope of business activities, number and location of the firm's offices, the nature and complexity of the products and services offered by the firm, the volume of business done, the number of associated persons assigned to a location, the disciplinary history of registered representatives or associated persons, and any indicators of irregularities or misconduct (*i.e.*, "red flags"), etc. The procedures established and reviews conducted must provide that the quality of supervision at remote locations is sufficient to ensure compliance with applicable securities laws and regulations and with Exchange rules. A member organization must be especially diligent in establishing procedures and conducting reasonable reviews with respect to a non-branch location where a registered representative engages in securities activities. Based on the factors outlined above, member organizations may need

to impose reasonably designed supervisory procedures for certain locations or may need to provide for more frequent reviews of certain locations.

Proposed Supplementary Material .13 to Rule 3110 would provide additional guidance to proposed Rule 3110(c)(1)(C), which would require a member organization to inspect on a regular periodic schedule every non-branch location. In establishing a non-branch location inspection schedule, there is a general presumption that a non-branch location will be inspected at least every three years, even in the absence of any indicators of irregularities or misconduct (*i.e.*, "red flags"). If a member organization establishes a longer periodic inspection schedule, the member organization must document in its written supervisory and inspection procedures the factors used in determining that a longer periodic inspection cycle is appropriate.

Proposed Supplementary Material .14 to Rule 3110 would provide that a member organization's determination that it is not possible to comply with proposed Rule 3110(c)(3)(B) with respect to who is not allowed to conduct a location's inspection will generally arise in instances where:

- The member organization has only one office; or

- The member organization has a business model where small or single-person offices report directly to an OSJ manager who is also considered the offices' branch office manager.

Proposed Supplementary Material .15 to Rule 3110 would provide a definition for "associated person" for the purposes of proposed Rule 3110.

Proposed Rule 3120 (Supervisory Control System)

Proposed Rule 3120(a), which is based on FINRA Rule 3120(a), would provide that each member organization must designate and specifically identify to the Exchange one or more principals who must establish, maintain, and enforce a system of supervisory control policies and procedures that:

- Test and verify that the member organization's supervisory procedures are reasonably designed with respect to the activities of the member organization and its associated persons, to achieve compliance with applicable securities laws and regulations, and with applicable Exchange rules; and

- Create additional or amend supervisory procedures where the need is identified by such testing and verification.

Similar to the requirements of current Rule 342.30, the designated principal or

principals would be required to submit to the member organization's senior management no less than annually, a report detailing each member organization's system of supervisory controls, the summary of the test results and significant identified exceptions, and any additional or amended supervisory procedures created in response to the test results.

Proposed Rule 3120(b) would provide that each report provided to senior management pursuant to proposed Rule 3120(a) in the calendar year following a calendar year in which a member organization reported \$200 million or more in gross revenue must include, to the extent applicable to the member organization's business:

- A tabulation of the reports pertaining to customer complaints and internal investigations made to the Exchange during the preceding year; and

- Discussion of the preceding year's compliance efforts, including procedures and educational programs, in each of the following areas:

- Trading and market activities;
- Investment banking activities;
- Antifraud and sales practices;
- Finance and operations;
- Supervision; and
- Anti-money laundering.

The categories listed above are incorporated from the annual report content requirements of current Rule 342.30, which apply to all member organizations regardless of revenue. The proposed rule change seeks to mitigate compliance costs and burdens with respect to proposed Rule 3120's annual reporting requirements by requiring that only member organizations reporting \$200 million or more in gross revenues in the preceding year include in their annual reports supplemental information from current Rule 342.30's annual report content requirements. The Exchange also believes that the proposed threshold strikes the appropriate balance as it encompasses larger member organizations, member organizations engaged in significant underwriting activities and substantial trading activities or market making business, and member organizations with extensive sales platforms.

Proposed Rule 3120(c) would provide that, for purposes of proposed Rule 3120(b), "gross revenue" is defined as:

- Total revenue as reported on FOCUS Form Part II or IIA (line item 4030) less commodities revenue (line item 3990), if applicable; or
- Total revenue as reported on FOCUS Form Part II CSE (line item 4030) less, if applicable,

- Commissions on commodity transactions (line item 3991); and
- Commodities gains or losses (line items 3924 and 3904).

Proposed Supplementary Material .01 to Rule 3120 would provide a definition for “associated person” for the purposes of proposed Rule 3120.

Proposed Rule 3150 (Holding of Customer Mail)

Proposed Rule 3150(a) would provide that a member organization may hold mail for a customer who will not be receiving mail at his or her usual address, provided that:

- The member organization receives written instructions from the customer that include the time period during which the member organization is requested to hold the customer’s mail. If the requested time period included in the instructions is longer than three consecutive months (including any aggregation of time periods from prior requests), the customer’s instructions must include an acceptable reason for the request (e.g., safety or security concerns). Convenience is not an acceptable reason for holding mail longer than three months;
- The member organization:
- Informs the customer in writing of any alternate methods, such as email or access through the member organization’s Web site, that the customer may use to receive or monitor account activity and information; and
- Obtains the customer’s confirmation of the receipt of such information; and
- The member organization verifies at reasonable intervals that the customer’s instructions still apply.

Proposed Rule 3150(b) would provide that, during the time that a member organization is holding mail for a customer, the member organization must be able to communicate with the customer in a timely manner to provide important account information (e.g., privacy notices and the Securities Investor Protection Corporation information disclosures required by Rule 2266), as necessary.

Proposed Rule 3150(c) would provide that a member organization holding a customer’s mail pursuant to proposed Rule 3150 must take actions reasonably designed to ensure that the customer’s mail is not tampered with, held without the customer’s consent, or used by an associated person of the member organization in any manner that would violate Exchange rules or the federal securities laws.

The Exchange currently does not have a rule comparable to proposed Rule 3150. The Exchange believes that

adding proposed Rule 3150 would help protect customers.

Proposed Supplementary Material .01 to Rule 3150 would provide a definition for “associated person” for the purposes of proposed Rule 3150.

Proposed Rule 3170 (Tape Recording of Registered Persons by Certain Firms)

Proposed Rule 3170(a) would provide the following definitions for purposes of proposed Rule 3170:

- The term “registered person” would mean any person registered with the Exchange.
- The term “disciplined firm” would mean:
 - A member organization that, in connection with sales practices involving the offer, purchase, or sale of any security, has been expelled from membership or participation in any securities industry SRO or is subject to an order of the SEC revoking its registration as a broker-dealer;
 - A futures commission merchant or introducing broker that has been formally charged by either the Commodity Futures Trading Commission or a registered futures association with deceptive telemarketing practices or promotional material relating to security futures, those charges have been resolved, and the futures commission merchant or introducing broker has been closed down and permanently barred from the futures industry as a result of those charges; or
 - A futures commission merchant or introducing broker that, in connection with sales practices involving the offer, purchase, or sale of security futures is subject to an order of the SEC revoking its registration as a broker or dealer.
- The term “disciplinary history” would mean a finding of a violation by a registered person in the past five years by the SEC, an SRO, or a foreign financial regulatory authority of one or more of the following provisions (or comparable foreign provision) or rules or regulations thereunder:
 - Violations of the types enumerated in Section 15(b)(4)(E) of the Act;
 - Section 15(c) of the Act;
 - Section 17(a) of the Securities Act of 1933;
 - Rules 10b–5 and 15c–1 through 15c–9 under the Act;
 - NASD Rule 2110 (Standards of Commercial Honor and Principles of Trade) or FINRA Rule 2010 (Standards of Commercial Honor and Principles of Trade) or NYSE Rule 2010 (Standards of Commercial Honor and Principles of Trade) or NYSE Rule 476(a)(6) (Failure to Observe High Standards of Commercial Honor and Just and

Equitable Principles of Trade) (only if the finding of a violation of NASD Rule 2110, FINRA Rule 2010, NYSE Rule 2010 or NYSE Rule 476(a)(6) is for unauthorized trading, churning, conversion, material misrepresentations or omissions to a customer, front-running, trading ahead of research reports or excessive markups), FINRA Rule 5280 (Trading Ahead of Research Reports), NASD Rule 2120 (Use of Manipulative, Deceptive or Other Fraudulent Devices) or FINRA Rule 2020 (Use of Manipulative, Deceptive or Other Fraudulent Devices) or NYSE Rule 2020 (Use of Manipulative, Deceptive or Other Fraudulent Devices) or NYSE Rule 476(a)(5) (effecting any transaction in, or inducing the purchase or sale of, any security by means of any manipulative, deceptive or other fraudulent device or contrivance), NASD Rule 2310 (Recommendations to Customers (Suitability)) or FINRA Rule 2111 (Suitability) or NYSE Rule 405 (Diligence as to Accounts), NASD Rule 2330 (Customers’ Securities or Funds) or FINRA Rule 2150 (Improper Use of Customers’ Securities or Funds; Prohibition Against Guarantees and Sharing in Accounts) or NYSE Rule 2150 (Improper Use of Customers’ Securities or Funds; Prohibition Against Guarantees and Sharing in Accounts), NASD Rule 2440 (Fair Prices and Commissions), NASD Rule 3010 (Supervision) or FINRA Rule 3110 (Supervision) or NYSE Rule 3110 (Supervision) or NYSE Rule 342 (Offices—Approval, Supervision and Control) (failure to supervise only for both NASD Rule 3010, FINRA Rule 3110, NYSE Rule 3110 or Rule 342), NASD Rule 3310 (Publication of Transactions and Quotations) or FINRA Rule 5210 (Publication of Transactions and Quotations) or NYSE Rule 5210 (Publication of Transactions and Quotations), and NASD Rule 3330 (Payment Designed to Influence Market Prices, Other than Paid Advertising) or FINRA Rule 5230 (Payments Involving Publications that Influence the Market Price of a Security); and MSRB Rules G–19, G–30, and G–37(b) & (c).

• The term “tape recording” would include without limitation, any electronic or digital recording that meets the requirements of proposed Rule 3170.

• The term “taping firm” would mean:

- A member organization with at least five but fewer than ten registered persons, where 40% or more of its registered persons have been associated with one or more disciplined firms in a registered capacity within the last three years;

- A member organization with at least ten but fewer than twenty registered persons, where four or more of its registered persons have been associated with one or more disciplined firms in a registered capacity within the last three years;

- A member organization with at least twenty registered persons where 20% or more of its registered persons have been associated with one or more disciplined firms in a registered capacity within the last three years.

- For purposes of calculating the number of registered persons who have been associated with one or more disciplined firms in a registered capacity within the last three years pursuant to proposed Rule 3170(a)(5), member organizations should not include registered persons who:

- Have been registered for an aggregate total of 90 days or less with one or more disciplined firms within the past three years; and

- Do not have a disciplinary history.

Proposed Rule 3170(b) would provide that each member organization that either is notified by the Exchange or otherwise has actual knowledge that it is a taping firm must establish, maintain, and enforce special written procedures for supervising the telemarketing activities of all of its registered persons. A taping firm required to establish, maintain, and enforce special written procedures pursuant to proposed Rule 3170(b) would be required to establish and implement the procedures within 60 days of receiving notice from the Exchange or obtaining actual knowledge that it is a taping firm. The procedures required by proposed Rule 3170(b) would include procedures for tape recording all telephone conversations between the taping firm's registered persons and both existing and potential customers and for reviewing the tape recordings to ensure compliance with applicable securities laws and regulations and applicable Exchange rules. The procedures must be appropriate for the taping firm's business, size, structure, and customers, and must be maintained for a period of three years from the date that the taping firm establishes and implements the procedures. All tape recordings made pursuant to the requirements of proposed Rule 3170(b) must be retained for a period of not less than three years from the date the tape was created, the first two years in an easily accessible place. Each taping firm would be required to catalog the retained tapes by registered person and date. By the 30th day of the month following the end of each calendar quarter, each taping firm

subject to the requirements of proposed Rule 3170(b) would be required to submit to the Exchange a report on the taping firm's supervision of the telemarketing activities of its registered persons.

Proposed Rule 3170(c) would provide that a member organization that becomes a taping firm for the first time may reduce its staffing levels to fall below the threshold levels within 30 days after receiving notice from the Exchange pursuant to the provisions of proposed Rule 3170(b)(1) or obtaining actual knowledge that it is a taping firm, provided the member organization promptly notifies the Exchange's Department of Member Regulation in writing of its becoming subject to the Rule. Once the member organization has reduced its staffing levels to fall below the threshold levels, it must not rehire a person terminated to accomplish the staff reduction for a period of 180 days. On or prior to reducing staffing levels pursuant to proposed Rule 3170(c), a member organization would be required to provide the Exchange's Department of Member Regulation with written notice identifying the terminated person(s).

Proposed Rule 3170(d) would provide that, pursuant to the Rule 9600 Series, the Exchange could, in exceptional circumstances, taking into consideration all relevant factors, exempt any taping firm unconditionally or on specified terms and conditions from the requirements of proposed Rule 3170. A taping firm seeking an exemption would be required to file a written application pursuant to the Rule 9600 Series within 30 days after receiving notice from the Exchange or obtaining actual knowledge that it is a taping firm. A member organization that becomes a taping firm for the first time could elect to reduce its staffing levels pursuant to the provisions of proposed Rule 3170(c) or, alternatively, to seek an exemption pursuant to proposed Rule 3170(d), as appropriate. A taping firm would not be able to seek relief from proposed Rule 3170 by both reducing its staffing levels pursuant to proposed Rule 3170(c) and requesting an exemption.

The Exchange does not currently have a rule comparable to proposed Rule 3170. The Exchange believes that adopting proposed Rule 3170 will provide for more effective supervision of member organizations that have a significant number of registered persons with disciplinary history, thereby resulting in enhanced customer protection.

Conforming Changes

The Exchange also proposes to make certain conforming changes to Rules 36,

70, 86, 345, 405, 407, 408,²⁰ 410, 416A, 472, 476A, 2210, and 9217 to delete or update cross-references to the proposed rules as applicable. The Exchange also proposes certain technical changes within Rule 86²¹ and 345.10²² that are unrelated to this proposal.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,²³ in general, and furthers the objectives of Section 6(b)(5) of the Act,²⁴ in particular, because it is designed to promote just and equitable principles of trade and to remove impediments to and perfect the mechanism of a free and open market and a national market system. Specifically, the Exchange believes that the proposed rule change supports the objectives of the Act by providing greater harmonization between Exchange rules and FINRA rules of similar purpose, resulting in less burdensome and more efficient regulatory compliance. In particular, Exchange member organizations that are also FINRA members are subject to Exchange supervisory rules and FINRA Rules 3110, 3120, 3150, and 3170, and harmonizing these rules by adopting proposed Rules 3110, 3120, 3150, and 3170 would promote just and equitable principles of trade by requiring a single standard for supervision. The Exchange believes that to the extent the Exchange has proposed changes that differ from the FINRA version of the Exchange rules, such changes are generally technical in nature and do not change the substance of the proposed rules. The Exchange also believes that the proposed rule change will update and add specificity to the requirements governing supervision, which will promote just and equitable principles of trade and help to protect investors. As such the Exchange believes that the proposed rule change meets the requirements of Section 6(b)(5) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The

²⁰ The Exchange also proposes to replace "allied member" in Rule 408 with "principal executive." See note 11, *supra*.

²¹ The Exchange proposes to update a reference to Rules 17a-3 and 17a-4 under the Act.

²² The Exchange proposes to delete a reference to "registered options representative."

²³ 15 U.S.C. 78f(b).

²⁴ 15 U.S.C. 78f(b)(5).

Exchange believes that the proposed rule change is not intended to address competitive issues but rather to achieve greater consistency between the Exchange's rules and FINRA's rules concerning supervision.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act²⁵ and Rule 19b-4(f)(6) thereunder.²⁶ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b-4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b-4(f)(6)²⁷ normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b-4(f)(6)(iii),²⁸ the Commission may designate a shorter period of time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, because it allows the Exchange to immediately conform its supervision rules to corresponding FINRA rules. This will ensure that Dual Members generally will be subject to a single set of rules governing supervision. As noted by the Exchange, the proposal would harmonize NYSE and FINRA rules, resulting in less burdensome and more efficient regulatory compliance. In addition, the proposal will update and

add specificity to the Exchange's requirements governing supervision, which will promote just and equitable principles of trade and help to protect investors. For these reasons, the Commission designates the proposed rule change to be operative upon filing.²⁹

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)³⁰ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NYSE-2014-56 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-NYSE-2014-56. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than

those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Section, 100 F Street NE., Washington, DC 20549-1090, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the NYSE's principal office. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSE-2014-56 and should be submitted on or before December 4, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³¹

Kevin M. O'Neill,
Deputy Secretary.

[FR Doc. 2014-26815 Filed 11-12-14; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-73549; File Nos. SR-BATS-2014-028; SR-BYX-2014-011; SR-EDGA-2014-16; SR-EDGX-2014-19]

Self-Regulatory Organizations; BATS Exchange, Inc.; BATS Y-Exchange, Inc.; EDGA Exchange, Inc.; EDGX Exchange, Inc.; Notice of Withdrawal of Proposed Rule Changes To Establish a New Market Data Product Called the BATS One Feed

November 6, 2014.

On July 14, 2014, BATS Exchange, Inc. ("BATS"), EDGA Exchange, Inc. ("EDGA"), and EDGX Exchange, Inc. ("EDGX") and, on July 18, 2014, BATS Y-Exchange, Inc. (together with BATS, EDGA, and EDGX, the "Exchanges") each filed with the Securities and Exchange Commission ("Commission") pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² proposed rule changes to establish the same new market data product called the BATS One Feed. The proposed rule changes were published for comment in the **Federal Register** on August 1, 2014.³

³¹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release Nos. 72688 (July 28, 2014), 79 FR 44941 (SR-BATS-2014-028); 72690 (July 28, 2014), 79 FR 44929 (SR-BYX-2014-

Continued

²⁵ 15 U.S.C. 78s(b)(3)(A)(iii).

²⁶ 17 CFR 240.19b-4(f)(6).

²⁷ 17 CFR 240.19b-4(f)(6).

²⁸ 17 CFR 240.19b-4(f)(6)(iii).

²⁹ For purposes of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

³⁰ 15 U.S.C. 78s(b)(2)(B).

Two comments on the proposals have been received.⁴ On September 15, 2014, the Commission extended the time to act on the proposals until October 30, 2014.⁵ On October 29, 2014, the Exchanges withdrew the proposals (SR-BATS-2014-028; SR-BYX-2014-011; SR-EDGA-2014-16; SR-EDGX-2014-19).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶

Kevin M. O'Neill,
Deputy Secretary.

[FR Doc. 2014-26812 Filed 11-12-14; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-73547; File No. SR-BOX-2014-25]

Self-Regulatory Organizations; BOX Options Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fee Schedule on the BOX Market LLC ("BOX") Options Facility

November 6, 2014.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on October 31, 2014, BOX Options Exchange LLC (the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposed rule change pursuant to Section 19(b)(3)(A)(ii) of the Act,³ and Rule 19b-4(f)(2) thereunder,⁴ which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange is filing with the Securities and Exchange Commission ("Commission") a proposed rule change to amend the Fee Schedule [sic] on the BOX Market LLC ("BOX") options facility. While changes to the fee schedule pursuant to this proposal will be effective upon filing, the changes will become operative on November 1, 2014. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's Internet Web site at <http://boxexchange.com>.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to make a number of changes to the BOX Fee Schedule.

Exchange Fees

Non-Auction Transactions

First, the Exchange proposes to amend Section I (Exchange Fees) to establish a subsection entitled "Non-

Auction Transactions."⁵ The Exchange then proposes to adopt the current fee structure for Non-Auction Transactions in Select Symbols for all Non-Auction transactions on BOX. With this change the Select Symbols fee structure outlined in Section I.C. of the BOX Fee Schedule will be removed.

Currently, Non-Auction Transactions in non-Select Symbols are subject to the fee structure outlined in Section I of the BOX Fee Schedule. For every Non-Auction Transaction, Public Customers are assessed a \$0.07 fee per contract and Professional Customers and Broker Dealers \$0.42 per contract. Market Makers are assessed a per contract fee based upon the Market Maker's Monthly ADV in all transactions executed on BOX, as calculated at the end of each month. All Non-Auction Transactions for that month are charged the same per contract fee according to the ADV achieved by the Market Maker, which ranges from \$0.13 to \$0.35.

In proposed Section I.A. (Non-Auction Transactions), the Exchange proposes to adopt a pricing model where the Exchange will assess transaction fees and credits dependent upon three factors: (i) The account type of the Participant submitting the order; (ii) whether the Participant is a liquidity provider or liquidity taker; and (iii) the account type of the contra party. Non-Auction Transactions in Penny Pilot Classes will also be assessed different fees or credits than Non-Auction Transactions in Non-Penny Pilot Classes.

The Exchange also proposes to specify that these transactions will now be exempt from the Liquidity Fees and Credits outlined in Section II of the BOX Fee Schedule. The proposed fee structure for all Non-Auction Transactions is as follows:

Account type	Contra party	Penny pilot classes		Non-penny pilot classes	
		Maker fee/credit	Taker fee/credit	Maker fee/credit	Taker fee/credit
Public Customer	Public Customer	\$0.00	\$0.00	\$0.00	\$0.00
	Professional Customer/Broker Dealer.	(0.22)	(0.22)	(0.57)	(0.57)
	Market Maker	(0.22)	(0.22)	(0.57)	(0.57)

011); 72689 (July 28, 2014), 79 FR 44917 (SR-EDGA-2014-16); and 72691 (July 28, 2014), 79 FR 44892 (SR-EDGX-2014-19).

⁴ See Letter from Sal Arnuk and Joe Saluzzi, Themis Trading LLC, to Elizabeth M. Murphy, Secretary, Commission, dated August 21, 2014; and Letter from Ira D. Hammerman, General Counsel, SIFMA, to Kevin M. O'Neill, Deputy Secretary,

Commission, dated August 22, 2014 (letters commenting on SR-BATS-2014-18).

⁵ See Securities Exchange Act Release Nos. 73101, 79 FR 56418 (Sept. 19, 2014) (SR-BATS-2014-028); 73102, 79 FR 56419 (Sept. 19, 2014) (SR-BYX-2014-011); 73098, 79 FR 56415 (Sept. 19, 2014) (EDGA-2014-16); and 73099, 79 FR 56418 (Sept. 19, 2014) (SR-EDGX-2014-19).

⁶ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A)(ii).

⁴ 17 CFR 240.19b-4(f)(2).

⁵ Non-Auction Transactions are those transactions executed on the BOX Book.

Account type	Contra party	Penny pilot classes		Non-penny pilot classes	
		Maker fee/credit	Taker fee/credit	Maker fee/credit	Taker fee/credit
Professional Customer or Broker Dealer.	Public Customer	0.55	0.59	0.90	0.94
	Professional Customer/Broker Dealer.	0.20	0.35	0.30	0.35
	Market Maker	0.20	0.39	0.30	0.39
Market Maker	Public Customer	0.51	0.55	0.85	0.90
	Professional Customer/Broker Dealer.	0.00	0.05	0.00	0.10
	Market Maker	0.10	0.29	0.10	0.29

For example, if a Public Customer submitted an order to the BOX Book in a Penny Pilot Class (making liquidity), the Public Customer would be credited \$0.22 if the order interacted with a Market Maker's order and the Market Maker (taking liquidity) would be charged \$0.55. To expand on this example, if the Market Maker instead submitted an order to the BOX Book in a Penny Pilot Class (making liquidity), the Market Maker would be charged \$0.51 if the order interacted with a Public Customer's order and the Public Customer (taking liquidity) would again be credited \$0.22.

Tiered Volume Rebate for Non-Auction Transactions

Accordingly, the Exchange proposes to adopt the same tiered volume-based rebate for Market Makers and Public Customers in Non-Auction Transactions that was previously applied to Non-Auction Transactions in Select Symbols. Specifically, Market Makers and Public Customers will receive a per contract rebate based on ADV considering all transactions executed on BOX by the Market Maker or Public Customer, respectively, as calculated at the end of each month. All Non-Auction Transactions for that month will receive

the same per contract rebate according to the ADV achieved by the Market Maker or Public Customer. However, the Exchange proposes to specify that Non-Auction Transactions where a Public Customer order interacts with another Public Customer order will be exempt from the per contract rebate listed below. These transactions will still count toward the Public Customer's monthly ADV.

The new per contract rebate for Market Makers and Public Customers in Non-Auction Transactions as set forth in Section I.A.1. of the BOX Fee Schedule will be as follows:

	Per contract rebate
Market Maker Monthly ADV:	
100,001 contracts and greater	(\$0.15)
60,001 contracts to 100,000 contracts	(0.10)
35,001 contracts to 60,000 contracts	(0.07)
10,001 contracts to 35,000 contracts	(0.03)
1 contract to 10,000 contracts	0.00
Public Customer Monthly ADV:	
35,001 contracts and greater	(0.10)
15,001 contracts to 35,000 contracts	(0.06)
5,001 contracts to 15,000 contracts	(0.03)
1 contract to 5,000 contracts	0.00

Auction Transactions

The Exchange then proposes to amend Section I (Exchange Fees) to establish a subsection entitled "Auction Transactions."⁶ The Auction Transactions fees for Public Customers, Professional Customers and Broker Dealers will remain unchanged. For Market Makers, the Exchange proposes

to adopt a fee of \$0.20 for PIP Orders, COPIP Orders and Agency Orders.⁷ Currently Market Makers are assessed a per contract fee based upon the Market Maker's Monthly ADV in all transactions executed on BOX, as calculated at the end of each month. All PIP, COPIP and Agency Orders for that month are charged the same per contract fee according to the ADV achieved by

the Market Maker, which ranges from \$0.13 to \$0.35. The Exchange then proposes to remove the Tiered Fee Schedule for Market Makers based upon Monthly Average Daily Volume in current Section I.B.

The new Auction Transactions as set forth in Section I.B. of the BOX Fee Schedule will be as follows:

⁶ Auction Transactions are those transactions executed through the Price Improvement Period ("PIP"), the Complex Order Price Improvement Period ("COPIP"), the Solicitation Auction mechanism, and the Facilitation Auction

mechanism. All COPIP transactions will be charged per contract per leg.

⁷ A PIP Order or COPIP Order is a Customer Order (an agency order for the account of either a customer or a broker-dealer) designated for the PIP

or COPIP, respectively. An Agency Order is a block-size order that an Order Flow Provider seeks to facilitate as agent through the Facilitation Auction or Solicitation Auction mechanism.

	Account type			
	Public customer	Professional customer	Broker dealer	Market maker
PIP Order, COPIP Order, or Agency Order.	\$0.00	\$0.37	\$0.37	\$0.20
Improvement Order in PIP or COPIP ⁸ .	0.15	0.37	0.37	0.30
Responses in the Solicitation or Facilitation Auction Mechanisms.	0.15	0.37	0.37	0.30
Primary Improvement Order, ⁹ Facilitation Order, or Solicitation Order.	Based on ADV, see Section I. B.1.	Based on ADV, see Section I. B.1.	Based on ADV, see Section I. B.1.	Based on ADV, see Section I. B.1.

Liquidity Fees and Credits

Since all Non-Auction Transactions will now fall under Section I [sic] the new fee structure and be exempt from Section II Liquidity Fees and Credits, BOX proposes to remove subsection C (Non-Auction Transactions) from Section II. With the removal of subsection C, the Exchange proposes to move the bullet regarding non-immediately marketable orders to Section II.A (PIP and COPIP Transactions). A non-immediately marketable order that executes against a PIP Order or a COPIP Order, therefore becoming an Unrelated Order, will continue to be charged as an Improvement Order for purposes of the BOX Fee Schedule.

The Exchange then proposes to edit the language in proposed Section II.C, formerly Section II.D. (Exempt Transactions) and add the following fees for transactions which occur on the opening or re-opening of trading. For these transactions, which are deemed neither to “add” nor “remove” liquidity, the Exchange proposes to assess a flat fee per contract of \$0.00 for Public Customers, \$0.20 for Professional Customers and Broker Dealers and \$0.12 for Market Makers. The Exchange also proposes to clarify that outbound Eligible Orders routed to an Away Exchange, as defined in Rule 15000 Series, remain subject to the fees outlined in Section IV. Eligible Orders Routed to an Away Exchange.

Finally, the Exchange proposes to remove the “Select Symbols” language in Section II.C. (Exempt Transactions) that states that Non-Auction Transactions in Select Symbols will be considered exempt from all liquidity fees and credits. With the proposed changes, all Non-Auction Transactions will be considered exempt.

⁸ An Improvement Order is a response to a PIP or COPIP auction.

⁹ A Primary Improvement Order is the matching contra order submitted to the PIP or COPIP on the opposite side of an agency order.

MNX

The Exchange also proposes to amend the Fee Schedule to remove the reference to the Mini Nasdaq 100 Index (NDX) [sic].

Because the Exchange has delisted the Mini-NDX[®] Index (MNX), the Exchange proposes to remove the reference to MNX from the BOX Fee Schedule. Currently, Section I (Exchange Fees) of the BOX Fee Schedule provides for a surcharge to be applied to options on any index traded on BOX; which includes a \$0.22 per contract surcharge for options on MNX. The Exchange has since delisted options on MNX and they are no longer traded on BOX. As such, no related surcharge will apply and the Exchange is proposing to remove the reference from the BOX Fee Schedule.

Other

Finally, the Exchange is proposing to make additional non-substantive changes to the Fee Schedule. Specifically, the Exchange is renumbering certain footnotes, headings and internal references to accommodate the above proposed changes to the Fee Schedule. The Exchange also proposes to move the BOX Volume Rebate from current Section I.E of the Fee Schedule to proposed Section I.B (Auction Transactions).

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Act, in general, and Section 6(b)(4) and 6(b)(5) of the Act,¹⁰ in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among BOX Participants and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers. The proposed changes will allow the Exchange to be competitive with other exchanges and to apply fees and credits in a manner that is equitable among all

BOX Participants. Further, the Exchange operates within a highly competitive market in which market participants can readily direct order flow to any other competing exchange if they determine fees at a particular exchange to be excessive.

Exchange Fees

Non-Auction Transactions

The Exchange believes adopting the current fee structure for Non-Auction Transactions in Select Symbols for all Non-Auction Transactions, regardless of symbol, is reasonable, equitable and not unfairly discriminatory. Even though the Select Symbol fee structure for Non-Auction Transactions was only adopted last month, it was well received by Participants and the industry and the Exchange believes it is appropriate to now apply it to all Non-Auction Transactions. The proposed fee structure is intended to attract order flow to the Exchange by offering all market participants incentives to submit their Non-Auction orders to the Exchange. The practice of providing additional incentives to increase order flow is, and has been, a common practice in the options markets.¹¹ Further, the Exchange believes it is appropriate to provide incentives for market participants which will result in greater liquidity and ultimately benefit all Participants trading on the Exchange.

The Exchange also believes it is equitable, reasonable and not unfairly discriminatory to assess fees and credits according to the account type of the Participant originating the order and the contra party. This proposed fee structure was recently adopted by the Exchange for Non-Auction Transactions

¹¹ See International Securities Exchange LLC (“ISE”) Schedule of Fees, Section I. Regular Order Fees and Rebates for Standard Options, Non-Select Symbols (page 6); NASDAQ OMX PHLX, (“PHLX”), Pricing Schedule Section B, “Customer Rebate Program”; and NYSE Arca, Inc (“Arca”) Options Fees and Charges, “Customer Monthly Posting Credit Tiers and Qualifications for Executions in Penny Pilot Issues” (page 4).

¹⁰ 15 U.S.C. 78f(b)(4) and (5).

in Select Symbols¹² and is similar to the model adopted by the Exchange for Complex Orders Fees¹³ and has been accepted by both the Commission and the industry.¹⁴ The result of this structure is that a Participant does not know the fee it will be charged when submitting certain orders. Therefore, the Participant must recognize that it could be charged the highest applicable fee on the Exchange's schedule, which may, instead, be lowered or changed to a credit depending upon how the order interacts. This structure has been favorably received by the industry and BOX Participants; therefore the Exchange is proposing to apply the same structure to all Non-Auction Transactions. After adopting this type of structure for Non-Auction Transactions, a Public Customer submitting an order on the BOX Book will recognize that it will not pay a fee for these transactions and that depending upon with whom the order executes, the Public Customer may receive an additional benefit for submitting the order. Likewise, a Professional Customer or Broker Dealer submitting an order will recognize that it will not be charged more than \$0.59 in Penny Pilot issues and \$0.94 in Non-Penny Pilot issues. The same is true for Market Makers, who will recognize that their maximum charge when submitting a Non-Auction order will be \$0.55 in Penny Pilot issues and \$0.90 in Non-Penny Pilot issues.

The Exchange believes that the proposed fees and credits for Public Customers in Non-Auction Transactions are reasonable. Under the proposed fee structure Public Customers will either pay a Maker fee of \$0.00 or receive a Maker/Taker credit of \$0.22 for Penny Pilot classes and \$0.57 for Non-Penny Pilot classes. These potential fees and credits are reasonable and will at all times be less than the current \$0.07 Exchange Fee that Public Customers pay in Non-Auction Transactions.

The Exchange believes providing a credit or charging no fee to Public Customers for all Non-Auction Transactions is equitable and not unfairly discriminatory. The securities

markets generally, and BOX in particular, have historically aimed to improve markets for investors and develop various features within the market structure for Public Customer benefit. Accordingly, the Exchange believes that charging no fee or providing a credit for Public Customers is appropriate and not unfairly discriminatory. Public Customers are less sophisticated than other Participants and the credit will help to attract a high level of Public Customer order flow to the BOX Book and create liquidity, which the Exchange believes will ultimately benefit all Participants trading on BOX.

Finally, the Exchange believes it is reasonable, equitable and not unfairly discriminatory to give Public Customers a credit when their orders execute against a non-Public Customer and, accordingly, charge non-Public Customers a higher fee when their orders execute against a Public Customer. As stated above, the Exchange aims to improve markets by developing features for the benefit of its Public Customers. Similar to the payment for order flow and other pricing models that have been adopted by the Exchange and other exchanges to attract Public Customer order flow, the Exchange increases fees to non-Public Customers in order to provide incentives for Public Customers. The Exchange believes that providing incentives for Non-Auction Transactions by Public Customers is reasonable and, ultimately, will benefit all Participants trading on the Exchange by attracting Public Customer order flow.

The Exchange believes that charging Professional Customers and Broker Dealers higher fees than Public Customers for Non-Auction Transactions is equitable and not unfairly discriminatory. Professional Customers, while Public Customers by virtue of not being Broker Dealers, generally engage in trading activity more similar to Broker Dealer proprietary trading accounts (submitting more than 390 standard orders per day on average). The Exchange believes that the higher level of trading activity from these Participants will draw a greater amount of BOX system resources than that of non-professional, Public Customers. Because this higher level of trading activity will result in greater ongoing operational costs, the Exchange aims to recover its costs by assessing Professional Customers and Broker Dealers higher fees for transactions.

The Exchange also believes it is equitable and not unfairly discriminatory for BOX Market Makers

to be assessed lower fees than Professional Customers and Broker Dealers for Non-Auction Transactions because of the significant contributions to overall market quality that Market Makers provide. Specifically, Market Makers can provide higher volumes of liquidity and lowering their fees will help attract a higher level of Market Maker order flow to the BOX Book and create liquidity, which the Exchange believes will ultimately benefit all Participants trading on BOX. As such, the Exchange believes it is appropriate that Market Makers be charged lower transaction fees than Professional Customers and Broker Dealers for Non-Auction Transactions.

The Exchange believes that the proposed fees and credits for all other Participants in Non-Auction Transactions are reasonable. Under the proposed fee structure, a Professional Customer or Broker Dealer making liquidity and interacting with a Professional Customer, Broker Dealer or Market Maker will either be charged a fee of \$0.20 for Penny Pilot Classes or \$0.30 for Non-Penny Pilot Classes. If the Professional Customer or Broker Dealer is instead taking liquidity in either Penny Pilot or Non-Penny Pilot Classes, it will be charged \$0.35 if it interacts with a Professional Customer or Broker Dealer and \$0.39 if it interacts with a Market Maker. The Exchange believes the fees listed above are reasonable as they are lower than the current \$0.42 Exchange Fee charged to Broker Dealers and Professional Customers in Non-Auction Transactions.

Similarly, in the proposed fee structure a Market Maker making liquidity in both Penny Pilot and Non-Penny Pilot Classes will either be charged a fee of \$0.00 for interacting with a Professional Customer or Broker Dealer or \$0.10 for interacting with another Market Maker. If the Market Maker is instead taking liquidity, it will be charged \$0.05 (for Penny Pilot Classes) and \$0.10 (for Non-Penny Pilot Classes) if it interacts with a Professional Customer or Broker Dealer. If a Market Maker is taking liquidity and interacts with another Market Maker they will be charged \$0.29 in all situations. The Exchange believes the fees listed above are reasonable as they are, in most situations, lower than the current \$0.13 to \$0.35 Exchange Fee range for Market Makers under the BOX Fee Schedule and are in line with what is currently charged by the industry.¹⁵

¹⁵ Many U.S. Options Exchanges do not differentiate their fees between auction and non-auction transactions. However, the general range for

¹² See Securities Exchange Act Release No. 73397 (October 21, 2014), 79 FR 63982 (October 27, 2014) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Amend the Fee Schedule on the BOX Market LLC Options Facility).

¹³ See Securities Exchange Act Release No. 71312 (January 15, 2014), 79 FR 3649 (January 22, 2014) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fee Schedule To Establish Fees for Complex Order Price Improvement Period ("COPIP") Transactions).

¹⁴ This type of structure was also adopted by NYSE Arca in 2012. See Securities Release No. 68405 (December 11, 2012), 77 FR 74719 (December 17, 2012) (SR-NYSEArca-2012-137).

The Exchange believes it is reasonable, equitable and not unfairly discriminatory for Professional Customers, Broker Dealers and Market Makers to be charged higher fees for both making and taking liquidity when interacting with Public Customers. In the proposed fee structure, a Professional Customer or Broker Dealer interacting with a Public Customer will be charged a \$0.55 Maker fee or \$0.59 Taker fee for Penny Pilot Classes and a \$0.90 Maker fee or \$0.94 Taker fee for Non-Penny Pilot Classes. Similarly a Market Maker interacting with a Public Customer will be charged a \$0.51 Maker fee or \$0.55 Taker fee for Penny Pilot Classes and a \$0.85 Maker fee or \$0.90 Taker fee for Non-Penny Pilot Classes. While these fees are higher than what these Participants are currently charged for Non-Auction Transactions in Non-Select Symbols, the Exchange believes they are reasonable as they are in line when compared to similar fees in the options industry.¹⁶ Further, as stated above, the Exchange believes charging a higher fee for interactions with a Public Customer is equitable and not unfairly discriminatory because it allows the Exchange to incentivize Public Customer order flow by offering credits to Public Customers in Non-Auction Transactions. The Exchange believes that providing incentives for Non-Auction Transactions by Public Customers will benefit all Participants trading on the Exchange by attracting this Public Customer order flow.

The Exchange believes it is reasonable, equitable and not unfairly discriminatory for Professional Customers, Broker Dealers and Market Makers to be charged a higher fee for orders removing liquidity when compared to the fee they receive for

orders that add liquidity. Charging a lower fee for orders that add liquidity will promote liquidity on the Exchange and ultimately benefit all participants on BOX. Further, the concept of incentivizing orders that add liquidity over orders that remove liquidity is commonly accepted within the industry as part of the "Make/Take" liquidity model.¹⁷

Further, the Exchange believes it is equitable and not unfairly discriminatory to charge the Professional Customer or Broker Dealer more for taking liquidity against a Market Maker than they are charged for taking liquidity against other Professional Customers or Broker Dealers. As stated above, the Exchange proposes to provide certain incentives to Market Makers because of the high volumes of liquidity they can provide and increasing fees for Professional Customers and Broker Dealers taking liquidity will allow the Exchange to offer these incentives, ultimately benefiting all Participants trading on BOX.

Finally, the Exchange also believes it is reasonable to charge Professional Customers, Broker Dealers, and Market Makers less for certain executions in Penny Pilot issues compared to Non-Penny Pilot issues because these classes are typically more actively traded; assessing lower fees will further incentivize order flow in Penny Pilot issues on the Exchange, ultimately benefiting all Participants trading on BOX. Additionally, the Exchange believes it is reasonable to give a greater credit to Public Customers for Non-Auction Transactions in Non-Penny Pilot issues as compared to Penny Pilot issues. Since these classes have wider spreads and are less actively traded, giving a larger credit will further incentivize Public Customers to trade in these classes, ultimately benefitting all Participants trading on BOX.

The Exchange believes that the proposed Non-Auction Transactions fee structure will keep the Exchange competitive with other exchanges and will be applied in an equitable manner among all BOX Participants. The Exchange believes the proposed fee structure is reasonable and competitive with fee structures in place on other exchanges. Further, the Exchange believes that the competitive marketplace impacts the fees proposed for BOX.

Tiered Volume Rebate for Non-Auction Transactions

BOX believes it is reasonable, equitable and not unfairly discriminatory to introduce tiered volume based rebates for Market Makers and Public Customers in all Non-Auction Transactions. Other exchanges employ similar incentive programs,¹⁸ and the Exchange believes that its proposed volume thresholds and rebates are reasonable and competitive when compared to incentive structures at other exchanges.

Additionally, the Exchange believes that the proposed volume thresholds are reasonable because they will incentivize Public Customers and Market Makers to direct order flow to the Exchange to obtain the benefit of the rebate, which will in turn benefit all market participants by increasing liquidity on the Exchange. The Exchange believes that its proposed volume threshold and rebate is competitive when compared to rebate structures at other exchanges. Finally, the Exchange believes it is reasonable to exempt Non-Auction Transactions where a Public Customer order interacts with another Public Customer order from the per contract rebate. The Exchange does not believe a rebate in this situation is appropriate, as neither Public Customer will be paying a fee for the transaction. Further, these transactions will still count toward the Public Customer's monthly ADV.

The Exchange also believes it is equitable and not unfairly discriminatory to only adopt these structures for Public Customers and Market Makers. The proposed volume credits are intended to further encourage Public Customer and Market Maker Non-Auction order flow to the Exchange. Increased Public Customer and Market Maker volume will provide greater liquidity, which benefits all market participants on the Exchange. The practice of incentivizing increased Public Customer order flow is common in the options markets. Further, Market Makers also provide significant contributions to overall market quality. Specifically, Market Makers can provide high volumes of liquidity and lowering their Non-Auction Transaction fees will potentially help attract a higher level of

Market Maker fees is between \$0.10 and \$0.89. See NASDAQ OMX BX ("BX") Options Pricing, Chapter XV, Sec. 2; BX charges both BX Options Market Makers and Non-Customer/Non-BX Options Market Makers a fee of \$0.46 to remove liquidity in Penny Pilot Options and a fee of \$0.89 to remove liquidity in Non-Penny Pilot Options, a fee to add liquidity in Penny Pilot Options of \$0.40 to BX Options Market Makers and \$0.45 to Non-Customer/Non-BX Options Market Makers, and a fee to add liquidity in Non-Penny Pilot Options of \$0.50 to BX Options Market Makers (or \$0.85 when interacting with Customer) and \$0.88 for Non-Customer/Non-BX Options Market Makers. See NYSE Arca Options ("Arca") Fees and Charges page 3; Arca charges NYSE Arca Market Makers \$0.16 for manual executions, \$0.49 to take liquidity in Penny Pilot Issues, and \$0.87 to take liquidity in Non Penny Pilot Issues. See International Securities Exchange ("ISE") Schedule of Fees, Section I; ISE charges Market Makers \$0.10 for making liquidity in select symbols and \$0.42 for taking liquidity in select symbols.

¹⁶ *Id.* Professional Customer and Broker Dealers are also charged anywhere from \$0.10 to \$0.89 within the option exchange fee schedules referenced above.

¹⁷ The "Make/Take" model is currently used by the International Securities Exchange LLC ("ISE") and NASDAQ OMX PHLX LLC ("PHLX").

¹⁸ See Section B of the PHLX Pricing Schedule entitled "Customer Rebate Program" and CBOE's Volume Incentive Program (VIP). CBOE's Volume Incentive Program ("VIP") pays certain tiered rebates to Trading Permit Holders for electronically executed multiply-listed option orders which include AIM orders. Note that these exchanges base these rebate programs on the percentage of total national Public Customer volume traded on their respective exchanges, which the Exchange is not proposing to do.

Market Maker order flow and create liquidity, which the Exchange believes will ultimately benefit all Participants trading on BOX.

Auction Transactions

The Exchange believes it reasonable to remove the tiered fee structure for Market Makers based upon ADV. The tiered fee structure was adopted to incentivize Market Makers to direct order flow to the Exchange, which the Exchange believes is now unnecessary with the adoption of the new Non-Auction Transactions fee structure as well as the Tiered Volume Rebates for Market Makers in Non-Auction Transactions. Additionally, in Auction Transactions Market Makers remain eligible for the BOX Volume Rebate for all PIP and COPIP Orders of 250 and under contracts. The Exchange believes it is reasonable to adopt a flat \$0.20 per contract fee for Market Makers in PIP Orders, COPIP Orders, and Agency Orders. Specifically, the Exchange believes the fee strikes the appropriate balance between the \$0.13 to \$0.35 fees that Market Makers are currently charged for these orders and is reasonable when compared to similar fees among the industry.¹⁹ Finally, the Exchange believes it is equitable and not unfairly discriminatory to charge a Market Maker less for PIP Orders, COPIP Orders, and Agency Orders than what is charged to Professional Customers and Broker Dealers. Generally, Market Makers have obligations on BOX that other Participants do not. They must maintain active two-sided markets in the classes in which they are appointed and must meet certain minimum quoting requirements. Market Makers can also provide high volumes of liquidity and assessing lower transaction fee [sic] may help attract a higher level of Market Maker order flow and create liquidity, which the Exchange believes will ultimately benefit all Participants trading on BOX.

Liquidity Fees and Credits

The Exchange believes that exempting all Non-Auction Transactions from Section II (Liquidity Fees and Credits) is reasonable, equitable and not unfairly discriminatory. The Exchange's Liquidity Fees and Credits are intended to attract order flow to the Exchange by offering incentives to all market participants to submit orders to the Exchange and the Exchange believes that the proposed fee structure will provide appropriate incentives to encourage Participants to submit Non-

Auction Transactions to the Exchange. The Exchange believes that exempting Non-Auction Transactions from liquidity fees and credits is reasonable compared to the similar fees and credits offered by the other exchanges. The Exchange believes exempting Non-Auction Transactions from liquidity fees and credits is not unfairly discriminatory as the exemption from the liquidity fees and credits applies equally to all Participants on the Exchange.

The Exchange believes it is reasonable edit [sic] the Exempt Transactions subsection and to assess a flat fee for transactions which occur on the opening or re-opening of trading and are deemed neither to "add" nor "remove" liquidity. With the proposed fee structure for Non-Auction Transactions, which assess fees and credits dependent upon whether the Participant is a liquidity provider or liquidity taker, transactions on the opening or re-opening will not being [sic] charged an Exchange fee. For example, under the proposed Non-Auction fee structure a transaction on the opening would not be charged an Exchange Fee under Section I of the BOX Fee Schedule. Instead the Exchange is proposing to ensure that these transactions are assessed a fee. The Exchange has previously had this type of fee within the BOX Fee Schedule²⁰ and other exchanges with liquidity fees and credits also spell out how these transactions are treated within their respective fee schedules.²¹ The Exchange believes assessing a flat fee of \$0.00 for Public Customers, \$0.20 for Professional Customers and Broker Dealers and \$0.12 for Market Makers is in line with the Non-Auction Transactions fees outlined in the new fee structure. The Exchange believes it is equitable and not unfairly discriminatory for Public Customers to be charged no fee for transactions which occur on the opening or re-opening of trading. As stated above, the Exchange aims to improve markets by developing features for the benefit of its Public Customers. The Exchange also believes it is equitable and not unfairly discriminatory to charge a Market Maker less for these transactions than what is charged to Professional Customers and

Broker Dealers; as stated above, Market Makers have obligations that other Participants do not and can also provide high volumes of liquidity that will ultimately benefit all Participants on the Exchange.

MNX

The Exchange believes it is reasonable to remove from the BOX Fee Schedule a reference to a fee that is no longer applicable as options on MNX have been delisted and are no longer traded on BOX. The Exchange also believes it is equitable and not unfairly discriminatory to remove all references to MNX as this applies equally to all Participants on the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange believes that adopting the proposed fee structure for all Non-Auction Transactions will not impose a burden on competition among various Exchange Participants. BOX currently assesses distinct standard contract Exchange Fees for different account and transaction types. The Exchange believes that applying a fee structure that is determined according to whether the order removes or adds liquidity, the account type of the Participant submitting the order, and the contra party will result in Participants being charged appropriately for these transactions. Submitting an order is entirely voluntary and Participants can determine which type of order they wish to submit, if any, to the Exchange.

Further, the Exchange believes that this proposal will enhance competition between exchanges because it is designed to allow the Exchange to better compete with other exchanges for order flow.

Finally, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing exchanges. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

¹⁹ See *supra*, note 15.

²⁰ See Securities Exchange Act Release No. 61342 (January 13, 2010), 75 FR 3503 (January 21, 2014) [sic] (Notice of Filing and Immediate Effectiveness of a [sic] Proposed Rule Change to Amend [sic] the Fee Schedule of the Boston Options Exchange Facility).

²¹ See ISE Gemini, LLC ("ISE Gemini") Schedule of Fees Section I, Footnote 4 and Section II, Footnote 4. See NASDAQ OMX BX, Inc. ("BX") Chapter XV Options Pricing Sec. 2(2). See NASDAQ Options Market LLC ("NOM") Chapter XV Options Pricing Sec. 2(2).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Exchange Act²² and Rule 19b-4(f)(2) thereunder,²³ because it establishes or changes a due, or fee.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend the rule change if it appears to the Commission that the action is necessary or appropriate in the public interest, for the protection of investors, or would otherwise further the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-BOX-2014-25 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090. All submissions should refer to File Number SR-BOX-2014-25. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule

change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-BOX-2014-25, and should be submitted on or before December 4, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁴

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014-26811 Filed 11-12-14; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-73541; File No. SR-BX-2014-055]

Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Cancel-Replacement Orders and Routing

November 6, 2014.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on October 28, 2014, NASDAQ OMX BX, Inc. ("BX" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

²⁴ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to add specificity to the Exchange's options trading rules. The Exchange proposes to define cancel-replacement orders and also describe a route timer at in Chapter VI, entitled "Trading Systems."

The text of the proposed rule change is available on the Exchange's Web site at <http://nasdaqomxbx.cchwallstreet.com>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to amend Chapter VI to add additional specificity to its rules. The Exchange proposes to amend Section 1, Definitions, to define a cancel-replacement order. The Exchange proposes to amend Section 11, Order Routing, to add greater specificity to the Rulebook concerning a route timer.

Cancel-Replacement Orders

A market participant today has the option of either sending in a cancel order and then separately sending in a new order which serves as a replacement of the original order (two separate messages) or sending a single cancel-replacement order in one message.

If an order is submitted to the System and then subsequently a cancel order is sent to the System cancelling the original order, the original order will be cancelled by the System provided the original order was not already filled partially or in its entirety. A subsequent replacement order would be treated as a new order by the System and will not

²² 15 U.S.C. 78s(b)(3)(A)(ii).

²³ 17 CFR 240.19b-4(f)(2).

retain the priority of the cancelled order.

An order that is entered as one single message ("cancel-replacement order") containing two orders (versus two messages as described above) will also result in the original order being cancelled, provided the original order was not already filled partially or in its entirety.³ The replacement order will be considered a new order by the System and will have time priority as of the time that order is entered into the System, except in the case that the replacement order only serves to reduce the size of the order. A cancel-replacement order which only reduces the size of the order will continue to retain the priority of the original order.⁴ The replacement order will not retain the priority of the cancelled order except when the replacement *reduces* the size of the order and all other terms and conditions are retained. This is similar to the manner in which partially executed orders are prioritized in the System.

By way of example, if the original order is for 600 contracts and a market participant submits a cancel-replacement order for 600 contracts and in doing so, amends a term or condition such as the order type, presuming the original order was not filled in its entirety or partially, the entire original order would be cancelled. If the original order is for 600 contracts and a market participant submits a cancel-replacement order for 600 contracts and in doing so, amends a term or condition such as the order type, and 600 contracts were already filled, the cancel-replacement order would be returned to the market participant. If the original order is for 600 contracts and a market participant submits a cancel-replacement order for 600 contracts and in doing so, amends a term or condition such as the order type, and 300 contracts were already filled, the order would be modified to 300 contracts. Finally, if the original order is for 600 contracts and a market participant submits a cancel-replacement order solely reducing the size of the order by 300 contracts, the order would be modified to 300 contracts and the original order would retain its priority. In the previous examples provided, the

orders would not retain the priority of the original orders.

The Exchange proposes to add the following definition in Chapter VI, Section 1, "Cancel-replacement order shall mean a single message for the immediate cancellation of a previously received order and the replacement of that order with a new order with new terms and conditions. If the previously placed order is already filled partially or in its entirety, the replacement order is automatically canceled or reduced by the number of contracts that were executed. The replacement order will not retain the priority of the cancelled order except when the replacement order reduces the size of the order and all other terms and conditions are retained." This language is being added to Section 1(e)(1) to reflect the manner in which cancel-replacement orders function today. This filing does not reflect a change to the System; rather, the Exchange is memorializing in its rules the manner in which cancel-replacement orders are treated today.

Route Timer

Today, the System provides a number of routing options pursuant to which orders are sent to other available market centers for potential execution, per the entering market participant's instructions.⁵ The System routing options are SEEK or SRCH. With SEEK and SRCH, an order will first check the System for available contracts for execution. After checking the System for available contracts, orders are sent to other available market centers for potential execution, per the entering firm's instructions.

The Exchange proposes to add language in a new Section 11(a)(1)(C) to specify that after an order is initially routed,⁶ pursuant to either the SEEK or SRCH routing option, the order will post to the book and will be routed after a time period ("Route Timer") not to exceed one second as specified by the Exchange on its Web site provided that the order's limit price would lock or cross other market center(s).⁷ If, during the Route Timer, any new interest arrives opposite the order that is equal to or better than the away best bid or

offer ("ABBO") price, the order will trade against such new interest at the ABBO price. Eligible unexecuted orders will be routed at the end of the Route Timer provided the order was not filled and the order's limit price would continue to lock or cross the ABBO. If an order was routed with either the SEEK or SRCH routing option, and has size after such routing, it will execute against contra side interest in the book, post in the book, and route again pursuant to the process described above, if applicable, if the order's limit price would lock or cross another market center(s).

This language is being added to Section 11 to reflect the manner in which the Exchange imposes a Route Timer on routed orders today to permit quote updates to occur prior to subsequent routing. This filing does not reflect a change to the System, rather the Exchange is memorializing in its rules the manner in which orders are routed today.

The Exchange also proposes to amend rule text in Section 11(a)(1)(A) of Chapter VI concerning the SEEK routing option. The Exchange proposes to add language which clarifies the differences between SEEK and SRCH routing options with respect to contracts that remain un-executed after routing and are posted on the book. The Exchange proposes to state, "Once on the book *at the limit price*, should the order subsequently be locked or crossed by another market center, the System will not route the order to the locking or crossing market center." The Exchange believes this language more clearly differentiates an order routed pursuant to SEEK as compared to the SRCH routing option. An order routed pursuant to the SEEK routing option is routable until it is posted at its limit price. Once posted at its limit price, an order routed pursuant to the SEEK routing option would not continue to route, as compared to an order routed pursuant to the SRCH routing option. An order routed pursuant to the SRCH routing option is routable for the life of the order. The routing functionality is similar to functionality currently on Phlx.⁸

The Exchange also proposes to correct a typographical error in Chapter VI, Section 11(a)(1).

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act⁹ in general, and furthers the

³ With cancel-replacement orders, the original order is automatically canceled or reduced by the number of contracts that were executed depending on the volume of the original order that was filled. The market participant is required to enter the original order reference number when a cancel-replacement order is sent to the System as one message.

⁴ When a cancel-replacement order is sent to the System as one message the original order number reference is maintained by the System.

⁵ Participants can designate orders as either available for routing or not available for routing. See Chapter VI, Sec. 11(a).

⁶ If an order is only partially routed the portion that was not routed will be posted to the book.

⁷ Pursuant to Section 11(c) of Chapter VI, orders sent by the System pursuant to the SEEK and SRCH routing options to other markets would not retain time priority with respect to other orders in the System. If an order routed pursuant to SEEK or SRCH is subsequently returned, in whole or in part, that order, or its remainder, will receive a new time stamp reflecting the time of its return to the System.

⁸ See Phlx Rule 1080(m).

⁹ 15 U.S.C. 78f(b).

objectives of Section 6(b)(5) of the Act¹⁰ in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that its proposal to define cancel-replacement orders will add transparency to the rules. The Exchange is not amending the manner in which the System handles these orders. The Exchange is memorializing, in its rules, the method by which orders are handled by the System. The Exchange is defining cancel-replacement orders within Chapter VI, Section 1.

Specifically, with respect to cancel-replacement orders that reduce size, the Exchange believes that allowing cancel-replacement orders where only size is reduced to retain the priority of the original order is consistent with the manner in which the Exchange treats partially executed orders, which similarly apply the priority of the executed portion of the order to the remaining portion of the order. In addition, by permitting market participants' orders to remain on the book with the original priority and reduced size, the Exchange is providing market participants an ability to reduce exposure. The Exchange believes that adding transparency and specificity to the Rules protects investors and the public interest by reducing the potential for investor confusion.

The Exchange is also memorializing the manner in which the Exchange routes unexecuted portions of an order that will be subsequently routed to other markets when it comes back and subsequently locks and/or crosses the market. The Exchange will continue to re-route eligible unexecuted orders pursuant to a Route Timer. Contracts which remain unexecuted will be posted to the book provided the order's limit price would not lock or cross the ABBO. Specifically, the Exchange is describing the Route Timer that applies to eligible unexecuted portions of an order which will be subsequently routed. The timer protects investors and the public interest by providing a brief time period to allow the opportunity for markets to update quotes prior to subsequent routes.

The Exchange seeks to add language concerning the specific manner in which the Exchange will handle the routed order by specifying the routing methods in which SEEK or SRCH orders will route to the away market(s). The Exchange is adding clarifying language to make clear that after an order is initially routed, pursuant to either the SEEK or SRCH routing option, the order will post to the book and will be routed after a time period ("Route Timer") not to exceed one second as specified by the Exchange on its Web site provided that the order would lock or cross other market center(s). If, during the Route Timer, any new interest arrives opposite the order that is equal to or better than the ABBO price, the order will trade against such new interest at the ABBO price. Eligible unexecuted orders will be routed at the end of the Route Timer provided the order was not filled and it would continue to lock or cross the ABBO. If an order was routed with either the SEEK or SRCH routing option, and has size after such routing, it will execute against contra side interest in the book, post in the book, and route again pursuant to the process described above, if applicable, if the order would lock or cross another market center(s).

Further, the proposal to amend rule text in Section 11(a)(1)(A) of Chapter VI concerning SEEK orders clarifies the differences between SEEK and SRCH routing options with respect to contracts that remain un-executed after routing and are posted on the book. The Exchange seeks to clearly note that once an order routed pursuant to the SEEK routing option is on the order book at the limit price, it will not route, despite the order locking or crossing another market center. The Exchange believes this language more clearly differentiates an order routed pursuant to the SEEK routing option as compared to SRCH routing option.

The Exchange believes this language adds specificity and detail to the rule text so that market participants may anticipate the manner in which orders are handled by the Exchange when routing. The Exchange believes that adding transparency and specificity to the Rules protects investors and the public interest by reducing the potential for investor confusion.

The Exchange's proposal is intended to provide additional specificity to the rules in the manner in which the System treats cancel-replacement orders and handles routing of eligible unexecuted portions of previously routed orders, which is designed to promote just and equitable principles of trade.

The Exchange is not proposing to amend the manner in which the System operates. Cancel-replacement orders have been treated in this fashion since BX Options was first launched. Further, the Routing Timer for subsequent routes has also been in place on BX Options since its launch. The Exchange is proposing these additions to the rules in order to provide greater specificity to the Exchange's rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

BX does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange is seeking to provide greater transparency in its rules. The amendments are non-substantive and would apply to all market participants in the same manner. Permitting cancel-replacement orders to retain their original priority does not impose a burden on competition because the priority is retained only in the instance that size alone is changed and only if it is reduced. Permitting all market participants to reduce their exposure without penalty does not burden competition, rather it promotes competition by allowing participants the ability to change their orders in a changing market, provided the order was not already partially filled or filled in its entirety.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act¹¹ and subparagraph (f)(6) of Rule 19b-4 thereunder.¹²

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in

¹⁰ 15 U.S.C. 78f(b)(5).

¹¹ 15 U.S.C. 78s(b)(3)(a)(ii).

¹² 17 CFR 240.19b-4(f)(6).

the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved. The Exchange has provided the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-BX-2014-055 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549. All submissions should refer to File Number SR-BX-2014-055. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal

identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-BX-2014-055 and should be submitted on or before December 4, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹³

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014-26808 Filed 11-12-14; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[File No. 500-1]

Order of Suspension of Trading; In the Matter of Kolasco Corp.

November 10, 2014.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Kolasco Corp. because of questions regarding control over the company and the accuracy of company information, including in filings with the Commission, concerning, among other things, the company's acting officers. Kolasco Corp. is a Nevada corporation with its principal place of business located in Toronto, Canada. Its stock is quoted on OTC Link, operated by OTC Markets Group Inc., under the ticker: KLSC.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed company.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed company is suspended for the period from 9:30 a.m. EST, on November 10, 2014 through 11:59 p.m. EST, on November 21, 2014.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2014-26959 Filed 11-10-14; 4:15 pm]

BILLING CODE 8011-01-P

SMALL BUSINESS ADMINISTRATION

Advisory Committee on Veterans Business Affairs

AGENCY: U.S. Small Business Administration.

ACTION: Notice of open Federal Advisory Committee Meeting.

SUMMARY: The SBA is issuing this notice to announce the location, date, time, and agenda for the next meeting of the Advisory Committee on Veterans Business Affairs. The meeting will be open to the public.

DATES: Wednesday, December 17, 2014 from 9 a.m. to 4 p.m.

ADDRESSES: U.S. Small Business Administration, 409 3rd Street SW., Washington, DC 20416. Room: Eisenhower Conference room C, located on the Concourse Level Floor.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a) (2) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), SBA announces the meeting of the Advisory Committee on Veterans Business Affairs. The Advisory Committee on Veterans Business Affairs serves as an independent source of advice and policy recommendation to the Administrator of the U.S. Small Business Administration.

The purpose of this meeting is scheduled as a full committee. It will focus on strategic planning, updates on past and current events and the ACVBA's objectives for 2015. For information regarding our veterans' resources and partners, please visit our Web site at www.sba.gov/vets.

FOR FURTHER INFORMATION CONTACT: The meeting is open to the public, however, advance notice of attendance is requested. Anyone wishing to attend and/or make a presentation to the Advisory Committee must contact Barbara Carson, by December 12, 2014, by email in order to be placed on the agenda. Comments for the Record should be emailed prior to the meeting for inclusion in the public record, verbal presentations; however, will be limited to five minutes in the interest of time and to accommodate as many presenters as possible. Written comments should be emailed to Barbara Carson Acting Associate Administrator, Office of Veterans Business Development, U.S. Small Business Administration, 409 3rd Street SW., Washington, DC 20416.

Additionally, if you need accommodations because of a disability or require additional information, please contact Barbara E. Carson, Designated Federal Official for the Advisory Committee on Veterans Business Affairs at (202) 205-6773; or by email at barbara.carson@sba.gov. For more information, please visit our Web site at www.sba.gov/vets.

¹³ 17 CFR 200.30-3(a)(12).

Dated: October 31, 2014.

Diana Doukas,

SBA Committee Management Officer.

[FR Doc. 2014-26777 Filed 11-12-14; 8:45 am]

BILLING CODE 8025-01-P

SMALL BUSINESS ADMINISTRATION

Notice of Open Federal Interagency Task Force Meeting

AGENCY: U.S. Small Business Administration.

ACTION: Notice of open Federal Interagency Task Force Meeting.

SUMMARY: The SBA is issuing this notice to announce the location, date, time, and agenda for its public meeting of the Interagency Task Force on Veterans Small Business Development. The meeting will be open to the public.

DATES: *Date and Time:* December 18, 2014, from 9:00 a.m. to 12:00 noon.

ADDRESSES: SBA Headquarters, 409 3rd Street SW., Washington, DC 20416, in the Eisenhower Conference Room B, Concourse Level.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), SBA announces the meeting of the Interagency Task Force on Veterans Small Business Development. The Task Force is established pursuant to Executive Order 13540 and focused on coordinating the efforts of Federal agencies to improve capital, business development opportunities and pre-established Federal contracting goals for small business concerns owned and controlled by veterans (VOB's) and service-disabled veterans (SDVOSB's). Moreover, the Task Force shall coordinate administrative and regulatory activities and develop proposals relating to "six focus areas": (1) Access to capital (loans, surety bonding and franchising); (2) Ensure achievement of pre-established contracting goals, including mentor protégé and matching with contracting opportunities; (3) Increase the integrity of certifications of status as a small business; (4) Reducing paperwork and administrative burdens in accessing business development and entrepreneurship opportunities; (5) Increasing and improving training and counseling services; and (6) Making other improvements to support veteran's business development by the Federal government. On November 1, 2011, the Interagency Task Force on Veterans Small Business Development submitted its first report to the President, which included 18 recommendations that were

applicable to the "six focus areas" identified above. The purpose of the meeting is to discuss progress on the recommendations and next steps identified by the Interagency Task Force (IATF) in the Fiscal Year (FY) 14 Annual Report. The agenda will include updates from each of the members, public comment, and planning for the FY 14 of the IATF's Annual Report. In addition, the Task Force will allow time to obtain public comment from individuals and representatives of organizations regarding the areas of focus.

FOR FURTHER INFORMATION CONTACT: The meeting is open to the public; however, advance notice of attendance is requested. Anyone wishing to attend and/or make a presentation to the Task Force must contact Barbara Carson, by December 12, 2014 by email in order to be placed on the agenda. Comments for the record should be applicable to the "six focus areas" of the Task Force and emailed prior to the meeting for inclusion in the public record, verbal presentations; however, will be limited to five minutes in the interest of time and to accommodate as many presenters as possible.

Written comments should be emailed to Barbara Carson, Acting Associate Administrator, Office of Veterans Business Development, U.S. Small Business Administration, 409 3rd Street SW., Washington, DC 20416, at the email address for the Task Force, vettaskforce@sba.gov. Additionally, if you need accommodations because of a disability or require additional information, please contact Cheryl Simms, Designated Federal Official for the Task Force at (202) 205-6773; or by email at cheryl.simms@sba.gov. For more information, please visit our Web site at www.sba.gov/vets.

Dated: October 30, 2014.

Diana Doukas,

SBA Committee Management Officer.

[FR Doc. 2014-26802 Filed 11-12-14; 8:45 am]

BILLING CODE P

DEPARTMENT OF STATE

[Public Notice: 8945]

Culturally Significant Objects Imported for Exhibition Determinations: "Collecting Paradise: Buddhist Art of Kashmir and its Legacies"

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March

27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236-3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition "Collecting Paradise: Buddhist Art of the Kashmir and its Legacies," imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Mary & Leigh Block Museum of Art, Evanston, Illinois, from on or about January 13, 2015, until on or about April 19, 2015, the Rubin Museum of Art, New York, New York, from on or about May 22, 2015, until on or about November 30, 2015, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the imported objects, contact Paul W. Manning, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202-632-6469). The mailing address is U.S. Department of State, SA-5, L/PD, Fifth Floor (Suite 5H03), Washington, DC 20522-0505.

Dated: November 4, 2014.

Kelly Keiderling,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2014-26902 Filed 11-12-14; 8:45 am]

BILLING CODE 4710-05-P

DEPARTMENT OF STATE

[Public Notice: 8946]

Culturally Significant Objects Imported for Exhibition Determinations: "Picturing Mary: Woman, Mother, Idea" Exhibition

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236-3 of August 28, 2000 (and, as

appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition "Picturing Mary: Woman, Mother, Idea," imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the National Museum of Women in the Arts, Washington, DC, from on or about December 5, 2014, until on or about April 12, 2015, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the exhibit objects, contact Julie Simpson, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202-632-6467). The mailing address is U.S. Department of State, SA-5, L/PA, Fifth Floor (Suite 5H03), Washington, DC 20522-0505.

Dated: November 4, 2014.

Kelly Keiderling,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2014-26901 Filed 11-12-14; 8:45 am]

BILLING CODE 4710-05-P

DEPARTMENT OF STATE

[Public Notice: 8947]

U.S. Advisory Commission on Public Diplomacy; Notice of Meeting

The U.S. Advisory Commission on Public Diplomacy will hold a public meeting from 10:00 a.m. until 12:00 p.m., Thursday, December 11, 2014 in Room 902 (ninth floor) of the Hart Senate Office Building, at the corner of Second Street and Constitution Ave. NE., Washington, DC 20002.

The meeting's topic will be on "A Report on United States Public Diplomacy and International Broadcasting Activity Worldwide" and will feature findings from the Commission's Congressionally-mandated Comprehensive Annual Report on State Department and Broadcasting Board of Governors-led foreign public engagement activities. Representatives from the State Department and the BBG will be in attendance to discuss the report, which focuses on both Washington and field-directed activities.

This meeting is open to the public, Members and staff of Congress, the State Department, Defense Department, the media, and other governmental and non-governmental organizations. To attend and make any requests for reasonable accommodation, email pdcommission@state.gov by 5 p.m. on Thursday, December 4, 2014. Please arrive for the meeting by 9:45 a.m. to allow for a prompt meeting start.

The United States Advisory Commission on Public Diplomacy appraises U.S. Government activities intended to understand, inform, and influence foreign publics. The Advisory Commission may conduct studies, inquiries, and meetings, as it deems necessary. It may assemble and disseminate information and issue reports and other publications, subject to the approval of the Chairperson, in consultation with the Executive Director. The Advisory Commission may undertake foreign travel in pursuit of its studies and coordinate, sponsor, or oversee projects, studies, events, or other activities that it deems desirable and necessary in fulfilling its functions.

The Commission consists of seven members appointed by the President, by and with the advice and consent of the Senate. The members of the Commission shall represent the public interest and shall be selected from a cross section of educational, communications, cultural, scientific, technical, public service, labor, business, and professional backgrounds. Not more than four members shall be from any one political party. The President designates a member to chair the Commission.

The current members of the Commission are: Mr. William Hybl of Colorado, Chairman; Ambassador Lyndon Olson of Texas, Vice Chairman; Mr. Sim Farar of California, Vice Chairman; Ambassador Penne Korth-Peacock of Texas; Ms. Lezlee Westine of Virginia; and Anne Terman Wedner of Illinois. One seat on the Commission is currently vacant.

The following individual has been nominated to the Commission but awaits Senate confirmation as of this writing: Alfredo Balsera of Florida.

To request further information about the meeting or the U.S. Advisory Commission on Public Diplomacy, you may contact its Executive Director, Katherine Brown, at BrownKA4@state.gov.

Dated: November 6, 2014.

Katherine Brown,

Executive Director, Department of State.

[FR Doc. 2014-26904 Filed 11-12-14; 8:45 am]

BILLING CODE 4710-11-P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary of Transportation

Notice of Availability of Guidance on Accelerated Decisionmaking in Environmental Reviews

AGENCY: Office of the Secretary of Transportation, Department of Transportation (DOT).

ACTION: Notice of availability.

SUMMARY: DOT is announcing the availability of guidance implementing Section 1319 of MAP-21, on Accelerated Decisionmaking in Environmental Reviews. This section of MAP-21 provides for the use of errata sheets on the Draft Environmental Impact Statement, in lieu of a Final EIS (FEIS), when the EIS has limited or factual changes. It also states that the lead agency under NEPA shall issue a combined FEIS and ROD unless circumstances exist to make it impracticable. This eliminates the 30-day wait period between the release of the FEIS and ROD. This guidance builds on the interim guidance that was released by FHWA and FTA in January 2013, but applies to the entire Department. The FHWA and FTA interim guidance is retained as a supplemental appendix specific to those agencies. The guidance is available at <http://www.dot.gov/office-policy/transportation-policy/guidance-accelerated-decision-making-environmental-reviews>.

FOR FURTHER INFORMATION CONTACT:

Rebecca Higgins, Department of Transportation, 1200 New Jersey Ave. SE, W84-318, Washington, DC 20590; email Rebecca.Higgins@dot.gov; telephone (202) 366-7098.

Issue Date: November 3, 2014.

Shoshana Lew, Deputy Assistant Secretary for Policy.

[FR Doc. 2014-26731 Filed 11-12-14; 8:45 am]

BILLING CODE 4910-9X-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Memorandum of Agreement for Replacing the Griffin—Spalding County Airport (6A2), Griffin, GA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Memorandum of Agreement.

SUMMARY: The FAA has entered into a Memorandum of Agreement for replacing the Griffin—Spalding County

Airport (6A2), in Griffin, Georgia with the City of Griffin, Spalding County, and the Griffin-Spalding County Airport Authority. This Agreement sets forth the parties' obligations and commitments with regard to planning and constructing a replacement airport.

DATES: December 15, 2014.

FOR FURTHER INFORMATION CONTACT:

Larry F. Clark, Manager, Federal Aviation Administration, Atlanta Airports District Office, 1701 Columbia Ave., Campus Building, Suite 2-260, College Park, GA 30337.

SUPPLEMENTARY INFORMATION: On October 28, 2014, the City of Griffin and Spalding County, herein referred to as the Sponsor, and the Griffin-Spalding County Airport Authority entered into a Memorandum of Agreement (Agreement) with the FAA for replacing the Griffin-Spalding County Airport (6A2) in Griffin, Georgia. This Agreement sets forth the parties' obligations and commitments with regard to planning and constructing a replacement airport and outlines the process the parties will undertake to decommission 6A2 in the future. Prior to decommissioning 6A2, the FAA will provide notice and an opportunity for public comment as required by 49 U.S.C. 47107(h)(2).

On September 26, 2014, the Federal Aviation Administration added the proposed Griffin-Spalding County Replacement Airport to its National Plan of Integrated Airport Systems. The runway length and airport design at the existing airport are insufficient to support aviation needs. The sponsor evaluated all reasonable and practicable alternatives to address these constraints and proposed construction of the replacement airport to the FAA. The FAA issued a Finding of No Significant Impact/Record of Decision for the proposed replacement airport on March 12, 2013.

Any person may inspect, by appointment, the Agreement in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT**.

In addition, any person may, upon appointment and request, inspect the Agreement, notice and other documents determined by the FAA to be related to the Agreement in person at the Griffin-Spalding County Airport, 1035 Hill Street, Griffin, GA 30224.

Issued in College Park, Georgia, on November 5, 2014.

Larry F. Clark,

Manager, FAA Atlanta Airports District Office.

[FR Doc. 2014-26800 Filed 11-12-14; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE-2014-116]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before December 3, 2014.

ADDRESSES: You may send comments identified by Docket Number FAA-2014-0804 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to <http://www.regulations.gov> and follow the instructions for sending your comments electronically.

- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12-140, Washington, DC 20590.

- *Fax:* Fax comments to the Docket Management Facility at 202-493-2251.

- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477-78).

Docket: To read background documents or comments received, go to

<http://www.regulations.gov> at any time or to the Docket Management Facility in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jake Troutman, (202) 267-9521, 800 Independence Avenue SW., Washington, DC 20951.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on November 6, 2014.

James M. Crotty,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA-2014-0804

Petitioner: Allied Drones

Section of 14 CFR: Part 21 Subpart H, 45.23(b), 61.113(a) and (b), 91.3(a) and (c), 91.7(a), 91.9(b)(2), 91.103, 91.109, 91.119, 91.121, 91.151(a), 91.203(a) and (b), 91.405(a), 91.407(a)(1), 91.409(a)(2), and 91.417(a) and (b).

Description of Relief Sought: The petitioner, developer and operator of tether-powered small unmanned aircraft systems (sUAS), is seeking an exemption to commercially operate their tether-powered sUAS, weighing 55 pounds or less, to conduct aerial infrastructure inspections and surveys for the bridge, tower, and building construction and maintenance industries.

[FR Doc. 2014-26885 Filed 11-12-14; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE-2014-122]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and

must be received on or before December 3, 2014.

ADDRESSES: You may send comments identified by Docket Number FAA–2014–0838 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to <http://www.regulations.gov> and follow the instructions for sending your comments electronically.

- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.

- *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.

- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: To read background documents or comments received, go to <http://www.regulations.gov> at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jake Troutman, (202) 267–9521, 800 Independence Avenue SW., Washington, DC, 20951.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on November 6, 2014.

James M. Crotty,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2014–0838

Petitioner: Southern Company Services, Inc.

Section of 14 CFR: parts 21 Subpart H, 45 Subpart C, 47, 49, 61.3(d), 61.31(d)(2), 61.113(a) and (b), 91.7(a), 91.9(b)(2), 91.105, 91.109, 91.119,

91.121, 91.151(a), 91.203(a) and (b), 91.213, 91.405(a) and (d), 91.407(a)(1), 91.409(a)(2), and 91.417(a) and (b).

Description of Relief Sought: The petitioner is seeking an exemption to commercially operate their small unmanned aircraft system (sUAS) to conduct research on the applicability of sUAS when assessing damage to power lines due to storm events and performing routine power line inspection.

[FR Doc. 2014–26872 Filed 11–12–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2014–129]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before December 3, 2014.

ADDRESSES: You may send comments identified by Docket Number FAA–2014–0802 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to <http://www.regulations.gov> and follow the instructions for sending your comments electronically.

- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.

- *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.

- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to [http://](http://www.regulations.gov)

www.regulations.gov, including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: To read background documents or comments received, go to <http://www.regulations.gov> at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Nia Daniels, (202) 267–7626, 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on November 6, 2014.

James M. Crotty,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2014–0802.

Petitioner: Chevron USA, Inc.

Section of 14 CFR Affected: 61.113(a) and (b); 91.103(b); 91.119; 91.121; 91.151(a); 91.405(a); 91.407(a)(1); 91.409(a)(2); and 91.417(a) and (b)

Description of Relief Sought: Chevron USA, Inc. is requesting an exemption for commercial operation of its small unmanned aircraft system for aerial imaging for safety and monitoring of controlled access oil and gas facilities using the Skycatch UAS.

[FR Doc. 2014–26875 Filed 11–12–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2014–133]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve

the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before December 3, 2014.

ADDRESSES: You may send comments identified by Docket Number FAA–2014–0816 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to <http://www.regulations.gov> and follow the instructions for sending your comments electronically.
- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.
- *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.
- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: To read background documents or comments received, go to <http://www.regulations.gov> at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Keira Jones (202) 267–4024, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on November 6, 2014.

James M. Crotty,
Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2014–0816

Petitioner: Asymmetric Technologies
Section of 14 CFR Affected: 14 CFR part 21, Subpart H; part 27; §§ 45.23(b); 45.27(a); 61.113(a) and (b); 91.7(a) and 91.9(b)(2); 91.103; 91.109(a); 91.119; 91.121; 91.151(a); 91.203(a) and (b); 91.405(a)(1); 91.407(a)(1); 91.409(a)(1); 91.417(a) and (b)

Description of Relief Sought:

Asymmetric Technologies seeks relief to conduct sUAS flight operations in support of a bridge inspection near US Highway 93 in Mohave County, Arizona.

[FR Doc. 2014–26883 Filed 11–12–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2014–128]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before December 3, 2014.

ADDRESSES: You may send comments identified by Docket Number FAA–2014–0873 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to <http://www.regulations.gov> and follow the instructions for sending your comments electronically.
- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.
- *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.

• *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: To read background documents or comments received, go to <http://www.regulations.gov> at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Nia Daniels, (202) 267–7626. 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on November 6, 2014.

James M. Crotty,
Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2014–0873

Petitioner: Advanced Aerial Inspection Resources, LLC

Section of 14 CFR Affected: 61.113 (a) and (b); 91.103; 91.119; 91.121; 91.151 (a); 91.405 (a); 91.407 (a)(1); 91.409 (a)(2); and 91.417(a) and (b)

Description of Relief Sought: AAIR intends to operate small unmanned aircraft systems equipped to conduct aerial photography or other multi-spectral imaging for the purpose of structural and/or conditional assessment of high voltage electrical transmission monopoles and towers, tall communication monopoles and towers, and large wind turbine monopole towers and blades.

[FR Doc. 2014–26884 Filed 11–12–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****[Summary Notice No. PE–2014–119]****Petition for Exemption; Summary of Petition Received****AGENCY:** Federal Aviation Administration (FAA), DOT.**ACTION:** Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before December 3, 2014.

ADDRESSES: You may send comments identified by Docket Number FAA–2014–0845 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to <http://www.regulations.gov> and follow the instructions for sending your comments electronically.
- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.
- *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.
- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: To read background documents or comments received, go to

<http://www.regulations.gov> at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Nia Daniels, (202) 267–7626. 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on November 6, 2014.

James M. Crotty,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2014–0845.

Petitioner: Perfect View Aerial Media, LLC.

Section of 14 CFR Affected: Part 21, Subpart H, part 27, 45.23(b), 45.27(a), 61.113, 91.7(a), 91.9(b)(2), 91.9(c), 91.103, 91.109(a), 91.119, 91.121, 91.203(a) and (b), 91.151(a), 91.405(a), 91.407(a)(1), 91.409(a)(2), 91.417(a) and (b).

Description of Relief Sought: Perfect View Aerial Media, LLC seeks an exemption to permit it to offer thermal and optical imaging and inspections of electric power infrastructure and to conduct flights for training and maintenance purposes in a sterile area free from hazards and persons, by using an unmanned aircraft system, the DJI S–1000.

[FR Doc. 2014–26879 Filed 11–12–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****[Summary Notice No. PE–2014–73]****Petition for Exemption; Summary of Petition Received****AGENCY:** Federal Aviation Administration (FAA), DOT.**ACTION:** Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and

must be received on or before December 3, 2014.

ADDRESSES: You may send comments identified by Docket Number FAA–2014–0496 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to <http://www.regulations.gov> and follow the instructions for sending your comments electronically.

- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.

- *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.

- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: To read background documents or comments received, go to <http://www.regulations.gov> at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Doug Lundgren, Airman Certification and Training Branch, (AFS–810), General Aviation and Commercial Division, FAA; telephone number (202) 385–9600, fax number (202) 385–9577, email at Douglas.lundgren@faa.gov; or Sandra K. Long, ARM–201, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591, email Sandra.long@faa.gov, phone (202) 267–4714.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on November 7, 2014.

Lirio Liu,

Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2014–0496.

Petitioner: Empire Airlines.

Section of 14 CFR Affected: 14 CFR 61.160(b)

Description of Relief Sought: The petitioner is seeking relief from sections 61.160(b) and 61.169. The relief sought would allow the petitioner to issue documentation to pilots employed by Empire Airlines to apply for an airline transport pilot certificate with reduced aeronautical experience. Empire Airlines seeks to utilize these pilots' initial basic indoctrination training, general subjects training, type rating training, and training that conforms to Advisory Circular 61.138, in lieu of an Associate's or Bachelor's degree program with corresponding aviation-related coursework at an institution of high education which has received an FAA Letter of Authorization.

[FR Doc. 2014–26848 Filed 11–12–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2014–123]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before December 3, 2014.

ADDRESSES: You may send comments identified by Docket Number FAA–2014–0842 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to <http://www.regulations.gov> and follow the instructions for sending your comments electronically.

- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.

- *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.

- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: To read background documents or comments received, go to <http://www.regulations.gov> at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jake Troutman, (202) 267–9521, 800 Independence Avenue SW., Washington, DC 20951.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on November 6, 2014.

James M. Crotty,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2014–0842.

Petitioner: Unmanned Systems, Inc.

Section of 14 CFR: Part 21 Subpart H, 91.119, and 91.151(a).

Description of Relief Sought: The petitioner is seeking an exemption to commercially operate their Sandstorm unmanned aerial system ("Sandstorm") for operations such as: Commercial film production; agriculture; aerial surveying; and patrolling in, remote areas (i.e. non-congested or non-populated areas, private or controlled-access property), in the continental United States.

[FR Doc. 2014–26871 Filed 11–12–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2014–111]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before December 3, 2014.

ADDRESSES: You may send comments identified by Docket Number FAA–2014–0824 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to <http://www.regulations.gov> and follow the instructions for sending your comments electronically.

- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.

- *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.

- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: To read background documents or comments received, go to

<http://www.regulations.gov> at any time or to the Docket Management Facility in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jake Troutman, (202) 267-9521, 800 Independence Avenue SW., Washington, DC, 20951.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on November 6, 2014.

James M. Crotty,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA-2014-0824.

Petitioner: Viafield.

Section of 14 CFR: parts 21 Subpart H, 45.23, 45.29, 61.23, 61.3, 61.113(a) and (b), 61.133(a), 91.7(a), 91.9, 91.109(a), 91.119, 91.121, 91.151(a), 91.203, 91.319(a)(1), 91.401, 91.403, 91.405, 91.407, 91.409, 91.411, 91.413, 91.415, 91.417, 91.419, and 91.421.

Description of Relief Sought: The petitioner, a member-owned agricultural cooperative with 18 locations serving northern Iowa and southern Minnesota, is seeking an exemption to commercially operate their eBee small unmanned aircraft systems (sUAS) for precision agricultural surveying.

[FR Doc. 2014-26877 Filed 11-12-14; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE-2014-125]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before December 3, 2014.

ADDRESSES: You may send comments identified by Docket Number FAA-2014-0855 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to <http://www.regulations.gov> and follow the instructions for sending your comments electronically.

- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12-140, Washington, DC 20590.

- *Fax:* Fax comments to the Docket Management Facility at 202-493-2251.

- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide.

Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477-78).

Docket: To read background documents or comments received, go to <http://www.regulations.gov> at any time or to the Docket Management Facility in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jake Troutman, (202) 267-9521, 800 Independence Avenue SW., Washington, DC, 20951.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on November 6, 2014.

James M. Crotty,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA-2014-0855

Petitioner: Commonwealth Edison Company

Section of 14 CFR: part 21 Subpart H, 43.7, 43.11, 45.11, 45.23(b), 45.25, 45.29, 47.3(b)(2), 47.31(c), 91.9(b)(2) and (c), 91.103(b)(2), 91.105, 91.109, 91.113(b), 91.115, 91.119(b) and (c), 91.121, 91.151, 91.203(a)(1) and (2),

91.215, 91.319(a)(1), 91.403, 91.405, 91.407, 91.409, and 91.417.

Description of Relief Sought: The petitioner, a northern Illinois-based electric utility, is requesting relief to commercially operate their small unmanned aircraft systems (sUAS) to test utility system monitoring by sUAS in a remote area of Cook and Will Counties, Illinois.

[FR Doc. 2014-26887 Filed 11-12-14; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE-2014-124]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before December 3, 2014.

ADDRESSES: You may send comments identified by Docket Number FAA-2014-0846 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to <http://www.regulations.gov> and follow the instructions for sending your comments electronically.

- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12-140, Washington, DC 20590.

- *Fax:* Fax comments to the Docket Management Facility at 202-493-2251.

- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to <http://www.regulations.gov>, including any

personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477-78).

Docket: To read background documents or comments received, go to <http://www.regulations.gov> at any time or to the Docket Management Facility in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jake Troutman, (202) 267-9521, 800 Independence Avenue SW., Washington, DC 20951.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, November 6, 2014.

James M. Crotty,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA-2014-0846.

Petitioner: State Farm Mutual Automobile Insurance Company.

Section of 14 CFR: Part 21 Subpart H, 45.23(b), 45.27, 61.113(a) and (b), 91.119(c), 91.121, 91.151(a), 91.405(a), 91.407(a)(1), 91.409(a), and 91.417(a) and (b).

Description of Relief Sought: The petitioner is seeking an exemption to commercially operate their small unmanned aircraft systems (sUAS) to obtain up-close images of State Farm policyholders' roofs and perform an in-depth analysis of the images to determine the nature and extent of damage to the roof surface.

[FR Doc. 2014-26874 Filed 11-12-14; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE-2014-113]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief

from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before December 3, 2014.

ADDRESSES: You may send comments identified by Docket Number FAA-2014-0825 using any of the following methods:

- **Government-wide rulemaking Web site:** Go to <http://www.regulations.gov> and follow the instructions for sending your comments electronically.

- **Mail:** Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12-140, Washington, DC 20590.

- **Fax:** Fax comments to the Docket Management Facility at 202-493-2251.

- **Hand Delivery:** Bring comments to the Docket Management Facility in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477-78).

Docket: To read background documents or comments received, go to <http://www.regulations.gov> at any time or to the Docket Management Facility in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jake Troutman, (202) 267-9521, 800 Independence Avenue SW., Washington, DC 20951.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on November 6, 2014.

James M. Crotty,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA-2014-0825.

Petitioner: Danis Building Construction Company.

Section of 14 CFR: Part 21 Subpart H, 45.23, 45.29, 91.9, 91.119, 91.121, 91.151, 91.203(a) and (b), 91.401, 91.403, 91.405, 91.407, 91.409, 91.411, 91.413, 91.415, and 91.417.

Description of Relief Sought: The petitioner, a general contractor, is seeking an exemption to commercially operate their small unmanned aircraft systems (sUAS), weighing 4.4 pounds or less, on their own sites in order to improve employee safety and ensure quality assurance for the structures they are creating.

[FR Doc. 2014-26876 Filed 11-12-14; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in California

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of limitation on claims for judicial review of actions by the California Department of Transportation (Caltrans), pursuant to 23 USC 327, and

SUMMARY: The FHWA, on behalf of Caltrans, is issuing this notice to announce actions taken by Caltrans, that are final within the meaning of 23 U.S.C. 139(l)(1). The actions relate to the Bayview Transportation Improvements Project (Federal-aid project number HP21L-5934(115)) affecting various streets within Bayview and Hunters Point in the City and County of San Francisco, State of California. Those actions grant approval for the project.

DATES: By this notice, the FHWA, on behalf of Caltrans, is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before April 13, 2015. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Boris Deunert, Senior Environmental Planner, Caltrans District 4 Office of Local Assistance, 12th Floor, 111 Grand

Avenue, Oakland, CA 94623, (Tel: 510 286 6371, Email: boris.deunert@dot.ca.gov) Office Hours: 7:00 a.m. to 4:30 p.m. Mon. to Fri., Pacific Standard Time

SUPPLEMENTARY INFORMATION: Effective July 1, 2007, the Federal Highway Administration (FHWA) assigned, and the California Department of Transportation (Caltrans) assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Notice is hereby given that Caltrans has taken final agency actions subject to 23 U.S.C. 139(I)(1) by issuing a Finding of No Significant Impact (FONSI) for the following highway project in the State of California: The Bayview Transportation Improvements project is a federally funded project sponsored by the Public Works Department of the City and County of San Francisco. The project aims to improve traffic operations, accommodate approved and planned growth, and develop a more direct access route from U.S. Highway 101 and Interstate 280 to the Candlestick Point and Hunters Point Shipyard areas of San Francisco. Within the project area, the proposals include new and improved roadways, transit improvements (including infrastructure for a Bus Rapid Transit and a new Transit Center), and bicycle and pedestrian improvements. The Caltrans Federal-aid project number is HP21L-5934 (115). The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Final Environmental Assessment (FEA) for the project, approved on 29 August 2014, and in the Finding of No Significant Impact (FONSI) issued on 29 August 2014, and in other documents in the Caltrans project records. The FEA, FONSI, and other project records are available by contacting Caltrans at the address provided above. The FEA and FONSI can be viewed and downloaded from the project Web site at <http://sfdpw.org/index.aspx?page=59>, or viewed at public libraries in the project area. This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including, but not limited to:

1. National Environmental Policy Act (NEPA) [42 U.S.C. 4321-4351]; Federal-Aid Highway Act [23 U.S.C. 109 and 23 U.S.C. 128]
2. Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303]
3. National Historic Preservation Act of 1966, as amended [16 U.S.C. 470 (f) et seq.]

4. Section 7 of the Endangered Species Act of 1973 (ESA) [16 U.S.C 1531-1544 and Section 1536]
5. Clean Air Act [42 U.S.C. 7401-7671 (q)]
6. Floodplain Management, Executive Order 11988
7. Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations, Executive Order 12898

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(I)(1).

Issued on: October 22, 2014.

Gary Sweeten,

North Team Leader, Project Delivery Team, Federal Highway Administration, Sacramento, California.

[FR Doc. 2014-26838 Filed 11-12-14; 8:45 am]

BILLING CODE 4910-RY-P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Availability Regarding a Record of Decision for the Virginia Avenue Tunnel Reconstruction Project in Washington, DC

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Availability Regarding a Record of Decision (ROD) for the Virginia Avenue Tunnel Reconstruction Project in Washington, DC.

SUMMARY: In accordance with the National Environmental Policy Act (NEPA) and Federal Highway Administration (FHWA) procedures, this notice announces the availability of the ROD regarding the Virginia Avenue Tunnel Reconstruction Project in Washington, DC. The Division Administrator, FHWA-District of Columbia signed the ROD on November 4, 2014.

ADDRESSES: The FHWA ROD for the Virginia Avenue Reconstruction Project can be viewed and downloaded from the project Web site at <http://www.virginiaavenuetunnel.com> or viewed at the following locations: Southeast Neighborhood Library, 403 7th Street SE., Washington, DC 20003; or the Southwest Neighborhood Library, 900 Wesley Place SW., Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Hicks, Environmental/Urban Engineer, 1990 K Street, Suite 510,

Washington, DC 20006-1103, (202) 219-3513; email: Michael.Hicks@dot.gov. The FHWA District of Columbia Division normal business hours are 8 a.m. to 4:30 p.m. (Eastern Time). You may also contact Mr. Faisal Hameed, Deputy Chief Engineer, Project Development & Environment, Infrastructure Project Management Administration (IPMA), District Department of Transportation, 55 M Street SE., Suite 500, Washington, DC 20003; telephone: 202-671-2326; email: Faisal.Hameed@dc.gov. The District Department of Transportation normal business hours are 8:15 a.m. to 4:45 p.m.

SUPPLEMENTARY INFORMATION: The Virginia Avenue Tunnel Reconstruction Project ROD was developed through preparation of the Final Environmental Impact Statement for the Virginia Avenue Tunnel Reconstruction Project in the District of Columbia. CSX Transportation, Inc. (CSX), the owner of the Virginia Avenue Tunnel, requested approval from FHWA to allow the short-term closure of I-695 ramps located at 6th and 8th Streets SE and occupancy of a portion of the 11th Street Bridge right-of-way located on Interstate 695 (I-695) to allow the reconstruction of the Virginia Avenue Tunnel. The tunnel is located in the Capitol Hill neighborhood of Washington, DC beneath eastbound Virginia Avenue SE. from 2nd Street SE. to 9th Street SE.; Virginia Avenue Park between 9th and 11th Streets; and the 11th Street Bridge right-of-way. The tunnel is also aligned on the south side of I-695. The final agency actions documented in the FHWA Record of Decision (ROD) were taken in full consideration of the information presented in the Draft Environmental Impact Statement approved on July 2, 2013, the Final Environmental Impact Statement approved on June 5, 2014, public and agency comments, and in other documents in the FHWA administrative record. The final agency actions also considered the DEIS public hearing held on July 31, 2013; and public meetings held on September 14, 2011, November 30, 2011, May 21, 2012, September 27, 2012, July 1, 2014 and July 31, 2014.

Authority: 23 CFR 771.127; 49 CFR 1.81, 1.85.

Issued On: November 4, 2014.

Joseph C. Lawson,

Division Administrator, District of Columbia.

[FR Doc. 2014-26622 Filed 11-12-14; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION**Federal Motor Carrier Safety Administration****[Docket No. FMCSA–2014–0133]****Agency Information Collection Activities; New Information Collection: State Commercial Driver's License Program Plan****AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.**ACTION:** Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for its review and approval and invites public comment. The FMCSA requests approval of a new ICR titled, “*State Commercial Driver's License Program Plan*,” as a result of requirements from Section 32305 of the Moving Ahead for Progress in the 21st Century Act (MAP–21), Public Law 112–141, dated July 6, 2012. The Act requires States to submit a plan to the Secretary describing the actions the State will take to address any deficiencies in the State's commercial driver's license (CDL) program, as identified by the Secretary in the most recent audit of the program. This ICR is needed to ensure that the States are complying with notification and recordkeeping requirements for information related to testing, licensing, violations, convictions and disqualifications and that the information is accurate, complete and transmitted and recorded within certain time periods as required by the Commercial Motor Vehicle Safety Act of 1986 (CMVSA), as amended.

DATES: We must receive your comments on or before January 12, 2015.**ADDRESSES:** You may submit comments identified by Federal Docket Management System (FDMS) Docket Number FMCSA–2014–0133 using any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- *Fax:* 1–202–493–2251.

- *Mail:* Docket Services; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.

- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5

p.m. e.t., Monday through Friday, except Federal holidays.

Instructions: All submissions must include the Agency name and docket number. For detailed instructions on submitting comments and additional information on the exemption process, see the Public Participation heading below. Note that all comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>, and follow the online instructions for accessing the dockets, or go to the street address listed above.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement for the Federal Docket Management System published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit <http://edocket.access.gpo.gov/2008/pdfE8–794.pdf>.

Public Participation: The Federal eRulemaking Portal is available 24 hours each day, 365 days each year. You can obtain electronic submission and retrieval help and guidelines under the “help” section of the Federal eRulemaking Portal Web site. If you want us to notify you that we received your comments, please include a self-addressed, stamped envelope or postcard, or print the acknowledgement page that appears after submitting comments online. Comments received after the comment closing date will be included in the docket and will be considered to the extent practicable.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Gordon, Office of State Programs, Commercial Driver's License Division (MC–ESL), Federal Motor Carrier Safety Administration, West Building 6th Floor, 1200 New Jersey Avenue SE., Washington, DC 20590. Telephone: 304–549–2651; email michael.gordon2@dot.gov.

SUPPLEMENTARY INFORMATION:

Background: The FMCSA is responsible for compliance and oversight of State Drivers Licensing Agencies (SDLAs). SDLAs are required to comply with the requirements of 49 CFR Part 384, titled “State Compliance with Commercial Driver's License

Program.” Section 32305 of MAP–21 amends 49 U.S.C. 31311 by adding paragraph (d) State Commercial Driver's License Program Plan requirements. In paragraph (d)(1), a State shall submit a plan to the Secretary of Transportation for complying with the requirements under this section during the period beginning on the date the plan is submitted and ending on September 30, 2016. In paragraph (d)(2), a plan submitted by a State under paragraph (d)(1) shall identify—(A) the actions that the State will take to address any deficiencies in the State's Commercial Driver's License Program, as identified by the Secretary in the most recent audit of the program; and (B) other actions that the State will take to comply with the requirements under subsection (a). Paragraph (d)(3) establishes the following: “(A) Implementation Schedule—A plan submitted by a State under paragraph (d)(1) shall include a schedule for the implementation of the actions identified under paragraph (d)(2). In establishing the schedule, the State shall prioritize actions to address any deficiencies highlighted by the Secretary as critical in the most recent audit of the program. (B) Deadline for Compliance with the requirements.—A plan submitted by a State under paragraph (1) shall include assurances that the State will take the necessary actions to comply with the requirements of subsection (a) not later than September 30, 2015.

This collection of information supports the DOT strategic goal of safety by requiring the States to assure that drivers of CMVs are properly licensed according to all applicable Federal requirements.

States will be required to complete a Commercial Driver's License Program Plan using a spreadsheet or pdf document that will be provided by FMCSA to each SDLA. The plan will be completed by the State and provided to FMCSA's CDL Division via the Automated Compliance Review System (ACRS), for review and concurrence. FMCSA may reject a State's Commercial Driver's License Program Plan if it is determined to be deficient by not adequately addressing the State's deficiencies, and/or assurances. Within the plan, the State will identify any deficiencies from the most recent audit and will be required to provide detailed information to demonstrate how the State will obtain compliance with Section 32305(a) of MAP–21 by September 30, 2015 and remain in compliance through September 30, 2016. This will enable FMCSA to determine a State's level of compliance with the CDL requirements. Previous to

MAP-21, there was no requirement for a SDLA to submit a Commercial Driver's License Program Plan.

The spreadsheet was developed by FMCSA. The spreadsheet will be sent to each SDLA. The SDLA will complete the spreadsheet and send directly to FMCSA via electronic transmission. FMCSA will then review each plan to assess each State's level of compliance with the CDL requirements. The spreadsheets will then be uploaded into FMCSA's Automated Compliance Review System (ACRS). Appropriate feedback will be provided from MC-ESL to each State after review.

Title: State Commercial Driver's License Program Plan.

OMB Control Number: 2126-00XX.

Type of Request: New collection.

Respondents: State Driver Licensing Agencies (SDLAs).

Estimated Number of Respondents: 51 State respondents.

Estimated Time per Response: 40 hours per SDLA.

Expiration Date: New collection.

Frequency of Response: One-time effort.

Estimated Total Annual Burden: 2,040 hours.

FMCSA estimates that each SDLA would need approximately 40 hours to complete the State Commercial Driver's License Program Plan and submit it to FMCSA. The Program Plan is completed on a one-time basis as required by section 32305 of MAP-21. There is no continuing information collection function associated with submitting this Program Plan. The Program Plan asks for information which is readily available to the filer.

For the purposes of the CDL program, the District of Columbia is considered a State. Therefore, there are 51 State responses with an estimated 40 hours per response to complete and submit the Program Plan to FMCSA.

The FMCSA estimates the SDLAs total annual burden is 2,040 hours (51 responses × 40 hours = 2,040 hours).

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the performance of FMCSA's functions; (2) the accuracy of the estimated burden; (3) ways for FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize or include your comments in the request for OMB's clearance of this information collection.

Issued under the authority of 49 CFR 1.87 on: November 4, 2014.

G. Kelly Regal,

Associate Administrator for Office of Research and Information Technology and Chief Information Officer.

[FR Doc. 2014-26850 Filed 11-12-14; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2010-0167]

RIN 2126-AB20

Electronic Logging Devices and Hours of Service Supporting Documents; Research Report on Attitudes of Truck Drivers and Carriers on the Use of Electronic Logging Devices and Driver Harassment

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of Availability of Research Report.

SUMMARY: On March 28, 2014, the Federal Motor Carrier Safety Administration (FMCSA) published a Supplemental Notice of Proposed Rulemaking (SNPRM) that proposed amendments to the Federal Motor Carrier Safety Regulations (FMCSRs) to establish: Minimum performance and design standards for hours-of-service (HOS) electronic logging devices (ELDs); requirements for the mandatory use of these devices by drivers currently required to prepare HOS records of duty status (RODS); requirements concerning HOS supporting documents; and measures to address concerns about harassment resulting from the mandatory use of ELDs. FMCSA announces the availability of a new report: "Attitudes of Truck Drivers and Carriers on the Use of Electronic Logging Devices and Driver Harassment." This project surveyed drivers on their attitudes regarding carrier harassment and examined whether reported harassment experiences varied due to the hours-of-service logging method used by the driver. The survey is an effort to further address the potential for harassment associated with ELDs and provides results that are consistent with the Agency's discussion of harassment in the ELD SNPRM. A copy of the report has been placed in the docket referenced at the beginning of this notice.

DATES: Comments must be received by December 15, 2014.

ADDRESSES: You may submit comments identified by Docket Number FMCSA-2010-0167 addressing the Research Report using any of the following methods:

- *Federal eRulemaking Portal:* Go to www.regulations.gov. Follow the on-line instructions for submitting comments.

- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12-140, Washington, DC 20590-0001.

- *Hand Delivery or Courier:* West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal Holidays.

- *Fax:* 1-202-493-2251.

To avoid duplication, please use only one of these four methods. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: For information concerning this report, please contact Mr. Albert Alvarez, Research Division of the Office of Analysis, Research, and Technology, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590-0001 or by telephone at 202-385-2377.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials pertaining to the report. This notice does not extend the earlier comment period pertaining to the ELD SNPRM published March 28, 2104.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA-2010-0167), indicate the specific section of the report to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov> and put the docket number, "FMCSA-2010-0167" in the "Keyword" box, and click "Search." When the new screen

appears, click on "Comment Now!" button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period pertaining to the report.

Viewing Comments and Documents

To view comments, as well as other documents available in the docket, go to <http://www.regulations.gov> and insert the docket number, "FMCSA-2010-0167" in the "Keyword" box and click "Search." Next, click the "Open Docket Folder" button and choose the document listed to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12-140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m. Monday through Friday, except Federal holidays.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at www.dot.gov/privacy.

II. The Research Report

This research report, titled, "Attitudes of Truck Drivers and Carriers on the Use of Electronic Logging Devices and Driver Harassment," examines the nature of harassment as viewed by truck drivers who are required to record their hours of service for the purposes of Federal reporting regulations. As it examines their perceptions, this research also reviews:

- Whether drivers' experiences and interactions with their carriers fall into the category of harassment.
- If these experiences occur with any regularity (once or twice a month or more).
- Whether these interactions are made possible as a result of the carrier

using HOS data collected via an ELD and whether it was a standalone ELD or part of a comprehensive system that included ELD capability.

These experiences and perceptions are reviewed both for truck drivers and for carrier personnel who manage truck drivers. The data collected from carrier personnel is similar to that collected from the drivers; that is, carriers were asked about the regularity of specific interactions with drivers at their firm, and whether the drivers might consider such actions (if they occur) harassment.

Drivers are analyzed according to the systems they used for logging their HOS (i.e., paper or ELD). Carrier personnel are also considered according to the primary HOS logging method used by their company.

Additional data was collected regarding attitudes about ELDs, reactions to definitions of harassment and coercion developed by the FMCSA, ways in which drivers are compensated and evaluated, and profiles of both the drivers and the carrier companies.

For the complete report, visit docket number FMCSA-2010-0167 or <http://www.fmcsa.dot.gov/safety/research-and-analysis/publications>.

Issued on: November 5, 2014.

G. Kelly Regal,

Associate Administrator, Office of Research and Information Technology and Chief Information Officer.

[FR Doc. 2014-26851 Filed 11-12-14; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Notice of Intent To Prepare an Environmental Impact Statement and Section 4(f) Evaluation for the I-20 East Transit Initiative Heavy Rail Transit Extension in DeKalb County, Georgia

AGENCY: Federal Transit Administration (FTA), (DOT).

ACTION: Notice of intent to prepare an environmental impact statement (EIS) and section 4(f) evaluation.

SUMMARY: The Federal Transit Administration (FTA) and the Metropolitan Atlanta Rapid Transit Authority (MARTA) intend to prepare an Environmental Impact Statement (EIS) and an evaluation per 49 U.S.C. 303 and 23 CFR part 774 ("Section 4(f)") for MARTA's I-20 East Heavy Rail Transit (HRT) Extension project, which would extend the existing Blue Line from the Indian Creek MARTA Station to the Mall at Stonecrest in eastern

DeKalb County. The EIS and Section 4(f) Evaluation will be prepared in accordance with regulations implementing the National Environmental Policy Act (NEPA), Section 4(f), as well as FTA's regulations and guidance implementing NEPA (40 CFR parts 1500 through 1508 and 23 CFR 771.105).

The extension of the existing MARTA Blue Line HRT was selected as a component of a multimodal Locally Preferred Alternative (LPA) resulting from the I-20 East Transit Initiative Detailed Corridor Analysis (DCA) completed in April 2012. The LPA also includes new Bus Rapid Transit (BRT) service along I-20 between downtown Atlanta and a new station at Wesley Chapel Road, east of I-285 in DeKalb County. The NEPA analysis for the BRT project is being advanced separately in an Environmental Assessment (EA).

The FTA originally published a NOI to perform federal environmental review for the entire I-20 East Transit Initiative LPA on August 28, 2012 (77 FR 52128). Project scoping activities for the I-20 East Transit Initiative LPA occurred in September 2012. In today's issue of the **Federal Register**, FTA is rescinding the August 28, 2012 NOI and issuing this notice to advise interested agencies and the public regarding updates to the Purpose and Need of the LPA that have occurred since the scoping activities. Specifically, the Purpose and Need for both the HRT Extension project and the BRT project have been revised to reflect their distinct and independent utility. The revised Purpose and Need for the HRT Extension project is presented later in this Notice.

SUPPLEMENTARY INFORMATION:

Description of the Proposed Project and Study Area

The first phase of the I-20 East Transit Initiative was the two year-long DCA. This DCA built upon a number of transit studies previously completed in the corridor and identified and evaluated transit improvements in the I-20 East Corridor from downtown Atlanta to the Mall at Stonecrest in eastern DeKalb County. The result of the DCA was the selection of a multimodal LPA comprised of an extension of the existing Blue heavy rail transit (HRT) line from MARTA's Indian Creek Station to the Mall at Stonecrest in eastern DeKalb County and new BRT service along I-20 between downtown Atlanta and a new station at Wesley Chapel Road, east of I-285 in DeKalb County.

The EIS, which focuses on the HRT Extension, has a study area that extends from the MARTA Indian Creek Station

south for 3.5 miles along I-285, then east for approximately 8.5 miles to the Mall at Stonecrest. The study area extends up to one-half mile on each side of the alignment in order to evaluate the direct, indirect, and cumulative impacts associated with the implementation of transit in the corridor.

Purpose and Need

The LPA presented to the public at Public Scoping Meetings on September 10, 11, and 13, 2012 included both the BRT and HRT components of the LPA. The BRT component is a separate project that is being addressed in an Environmental Assessment. The EIS Purpose and Need has been revised to specifically address the HRT Extension project as follows:

The purpose of the I-20 East HRT Extension project is to increase east-west mobility options between the City of Atlanta and Southeast DeKalb County and to improve transit access between residential areas and activity and employment centers both within the corridor and across the region—with minimal impacts to private property, historical resources and neighborhoods, and parklands by:

- Providing reliable and efficient transit service with sufficient capacity to address future travel demand projected in the I-20 corridor through a one-seat ride into downtown Atlanta and other activity centers in the corridor.
- Providing an alternative to automobile travel on congested roadways in the corridor, particularly the most congested areas east of I-285.
- Connecting to the existing MARTA rail network, thereby addressing a gap in the current system and improving regional transit accessibility and access to jobs for those who live and work in South DeKalb County.
- Completing an important link in the region's long term transit vision, Concept 3.
- Encouraging redevelopment and revitalization in key activity centers through investment opportunities around fixed transit stations.

The project is needed to:

- Meet the needs of corridor residents by providing a high capacity transit alternative to the current transportation system in a corridor that does not have sufficient capacity or planned capacity to address future travel demand. Few roadway investments are planned along the I-20 East Corridor between I-285 and the Mall at Stonecrest through 2040.
- Address increasing congestion and unreliable travel times in the corridor by providing an alternative to automobile trips into and out of Atlanta. Transit

travel times on the current MARTA and Georgia Regional Transportation Authority (GRTA) Xpress bus systems to destinations east of I-285 are expected to double between 2010 and 2040, with the majority of travel times greater than 80 minutes.

- Improve regional mobility and access to jobs and services for corridor residents, especially the transit-dependent population. The I-20 East corridor has a higher transit-dependent population than the metro Atlanta region and the State of Georgia, with approximately 10% zero-car households.

- Provide a direct link to the existing MARTA rail and bus network for residents of South DeKalb County, closing a critical gap in the existing network for the historically underserved and choice transit riders in the corridor. By offering a connection into the existing MARTA heavy rail system, residents and workers in the area would be provided with a one-seat ride to a direct connection to the City of Atlanta, the City of Decatur, DeKalb County and various regional employment centers. Citizens east of I-285 currently have a constrained number of options to access the MARTA system, requiring travel either by bus or by car, experiencing (and contributing to) congested roadway conditions and unreliable transit travel times due to operations in mixed traffic. This expansion will close a critical gap in the existing network by providing a proximate, direct, and reliable link for the traditionally underserved and choice transit riders in the corridor.

- Implement the region's future transit vision as well as regional and local land use and development plans for future investment in the corridor. Both the Atlanta Regional Commission's (ARC) Plan 2040 financially constrained regional transportation plan and the Concept 3 Transit Vision include the I-20 Corridor as a key link in the future regional transit network. The Regional Development Plan, DeKalb County Comprehensive Transportation Plan, and numerous local plans and studies incorporate fixed guideway transit as a catalyst for redevelopment in the I-20 East corridor.

- Promote reinvestment by providing the transit infrastructure needed to support investment in transit oriented development at key activity centers, such as the Wesley Chapel Road and Mall at Stonecrest. There is significant projected economic benefit for the corridor and the region through transit oriented development and related investment opportunities that will create jobs, revitalize key areas, and contribute to a transit oriented

development pattern served directly by the MARTA system.

Study Alternatives

MARTA completed a two year-long DCA that evaluated potential alignments and transit technologies for transit improvements in the I-20 East Corridor. From multiple alignment and transit technology alternatives, an LPA was selected and adopted by the MARTA Board of Directors in April 2012. The LPA included both a BRT and an HRT Extension project. The EIS will evaluate vertical and horizontal alternatives of the HRT portion of the adopted LPA as well as a No-Build alternative. These alternatives are described as follows:

1. No Build Alternative: This alternative reflects the existing transportation system plus any committed MARTA and Georgia Regional Transit Authority (GRTA) local and express bus service in the corridor, as well as all other transportation investments included in the Atlanta Regional Commission's (ARC) long-range transportation plan. ARC is the Metropolitan Planning Organization (MPO) for the Atlanta urbanized area. The I-20 East BRT project is included in the No-Build Alternative because its implementation is expected to precede that of the I-20 East HRT Extension by several years. NEPA requires the consideration of a No Build Alternative as a means of comparing and evaluating the impacts and benefits of the Build Alternative.

2. Build Alternative: The Build Alternative to be evaluated in the EIS is the extension of the existing MARTA east-west HRT line from the Indian Creek Station, south parallel to I-285, then east parallel to I-20 to the Mall at Stonecrest in eastern DeKalb County. The HRT service would include new stations at Covington Highway, Wesley Chapel Road, Panola Road, Lithonia Industrial Blvd., and the Mall at Stonecrest. It is expected that the HRT service would be implemented in two phases. The first phase would extend the existing MARTA east-west HRT line from Indian Creek Station to Wesley Chapel Road. The second phase would extend from Wesley Chapel Road to the Mall at Stonecrest. The HRT alignment would generally be located adjacent to the interstate and would utilize Georgia Department of Transportation (GDOT) right-of-way wherever possible.

The scope of the environmental analysis and procedures shared in the NOI published August 28, 2012 and at

the Public Scoping Meetings in September of 2012 remain unchanged.

Yvette G. Taylor,

Regional Administrator, FTA Region IV.

[FR Doc. 2014-26769 Filed 11-12-14; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Notice to Rescind Notice of Intent To Prepare an Environmental Impact Statement and Environmental Assessment for the I-20 East Transit Initiative in the City of Atlanta and DeKalb County, Georgia

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Rescind Notice of Intent to prepare an environmental impact statement and environmental assessment.

SUMMARY: The FTA in cooperation with the Metropolitan Atlanta Rapid Transit Authority (MARTA) is issuing this notice to advise the public that the Notice of Intent (NOI) to prepare an Environmental Impact Statement (EIS) and Environmental Assessment (EA) for the proposed public transportation improvement project in the City of Atlanta and DeKalb County, Georgia is being rescinded.

FOR FURTHER INFORMATION CONTACT: Mr. Stan Mitchell, Environmental Protection Specialist, Federal Transit Administration Region IV, 230 Peachtree Street NW., Atlanta, GA 30303, phone 404-865-5643, email stanley.a.mitchell@dot.gov.

SUPPLEMENTARY INFORMATION: The FTA, as lead federal agency, and MARTA published a NOI on August 28, 2012 (77 FR 52128) to prepare an EIS and EA for the MARTA I-20 East Transit Initiative project. This project would extend the existing east-west rail Heavy Rail Transit (HRT) line from the Indian Creek Station to the Mall at Stonecrest in eastern DeKalb County and also create a new Bus Rapid Transit (BRT) service along I-20 between downtown Atlanta and a new station at Wesley Chapel Road, east of I-285 in DeKalb County.

Since that time, FTA and MARTA have conducted scoping activities which have led to reevaluating the project in terms of Purpose and Need. Based on these scoping activities, FTA is rescinding the August 28, 2012 NOI, and, in today's issue of the **Federal Register**, is issuing a new NOI for the HRT extension. The environmental impacts of the BRT service along I-20

will be evaluated as a separate project in an environmental assessment. No changes will be made to the HRT or BRT services as described in the August 28, 2012 NOI. Comments and questions concerning the proposed action should be directed to FTA at the address provided above.

Yvette G. Taylor,

Regional Administrator, FTA Region IV.

[FR Doc. 2014-26768 Filed 11-12-14; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. DOT-MARAD 2014-0140]

Request for Comments of a Previously Approved Information Collection: Request for Waiver of Service Obligation, Request for Deferment of Service Obligation, Application for Review

AGENCY: Maritime Administration (MARAD), Department of Transportation.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below is being forwarded to the Office of Management and Budget (OMB) for review and comments. A **Federal Register** Notice with a 60-day comment period soliciting comments on the following information collection was published on July 14, 2014 (**Federal Register** 40836, Vol. 79, No. 134).

DATES: Comments must be submitted on or before December 15, 2014.

FOR FURTHER INFORMATION CONTACT: Anne Wehde, 202-366-5469, Office of Maritime Workforce Development, Maritime Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Title: Request for Waiver of Service Obligation, Request for Deferment of Service Obligation, Application for Review.

OMB Control Number: 2133-0510.

Type of Request: Renewal of a Previously Approved Information Collection.

Abstract: This information collection is essential for determining if a student or graduate of the United States Merchant Marine Academy (USMMA) or subsidized student or graduate of a

State maritime academy has a waiver able situation preventing them from fulfilling the requirements of a service obligation contract signed at the time of their enrollment in a Federal maritime training program. It also permits the Maritime Administration (MARAD) to determine if a graduate, who wishes to defer the service obligation to attend graduate school, is eligible to receive a deferment. Their service obligation is required by law.

Affected Public: U.S. Merchant Marine Academy students and graduates, and subsidized students and graduates.

Estimated Number of Respondents: 11.

Estimated Number of Responses: 11.

Annual Estimated Total Annual Burden Hours: 3.30.

ADDRESSES: Send comments regarding the burden estimate, including suggestions for reducing the burden, to the Office of Management and Budget, Attention: Desk Officer for the Office of the Secretary of Transportation, 725 17th Street NW., Washington, DC 20503. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.93.

Dated: November 6, 2014.

Julie P. Agarwal,

Secretary, Maritime Administration.

[FR Doc. 2014-26846 Filed 11-12-14; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. AB 290 (Sub-No. 370X)]

Norfolk Southern Railway Company—Discontinuance of Service Exemption—in Clermont, Brown and Adams Counties, Ohio

AGENCY: Surface Transportation Board, DOT.

ACTION: Correction to notice of petition for exemption.

On September 30, 2014, Norfolk Southern Railway Company (NSR) filed with the Surface Transportation Board a petition under 49 U.S.C. 10502 for exemption from the provisions of 49 U.S.C. 10903 to discontinue rail service over approximately 40.7 miles of rail line between milepost CT 32.83 at Williamsburg and milepost CT 73.50 at Plum Run in Clermont, Brown and Adams Counties, Ohio.

On October 20, 2014, notice of the petition for exemption was served and published in the **Federal Register** (79 FR 62,708). The notice erroneously stated that replies to the petition were due on or before October 30, 2014. This notice corrects that statement. Replies are due on or before November 10, 2014. All other information in the notice is correct.

Board decisions and notices are available on our Web site at “WWW.STB.DOT.GOV.”

Decided: November 6, 2014.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Brendetta S. Jones,
Clearance Clerk.

[FR Doc. 2014-26827 Filed 11-12-14; 8:45 am]

BILLING CODE 4915-01-P

U.S.-CHINA ECONOMIC AND SECURITY REVIEW COMMISSION

Notice of Open Public Hearing

AGENCY: U.S.-China Economic and Security Review Commission.

ACTION: Notice of Official Public Release of the Commission's 2014 Annual Report to Congress on November 20, 2014, Washington, DC.

SUMMARY: Notice is hereby given of the following public hearing of the U.S.-China Economic and Security Review Commission.

Name: Dennis C. Shea, Chairman of the U.S.-China Economic and Security Review Commission. The Commission is mandated by Congress to investigate, assess, and report to Congress annually on “the national security implications of the economic relationship between the United States and the People's Republic of China.” Pursuant to this mandate, the Commission will hold an official public release of the Commission's 2014 Annual Report to Congress on November 20, 2014.

Purpose of Meeting: Pursuant to this mandate, the Commission will hold an official public conference in Washington, DC to release the 2014 Annual Report on November 20, 2014.

The Commission is subject to the Federal Advisory Committee Act

(FACA) with the enactment of the Science, State, Justice, Commerce and Related Agencies Appropriations Act, 2006 that was signed into law on November 22, 2005 (Pub. L. 109-108). In accord with FACA, meetings of the Commission to make decisions concerning the substance and recommendations of its 2014 Annual Report to Congress are open to the public.

Topics Addressed

The Commission's 2014 Annual Report contains the following chapters and sections:

- Chapter 1: U.S.-China Economic and Trade Relations
 - Section 1: Year in Review: Economics and Trade
 - Section 2: U.S.-China Bilateral Trade and Economic Challenges
 - Section 3: China's Health Care Industry, Drug Safety, and Market Access for U.S. Medical Goods and Services
 - Section 4: U.S.-China Clean Energy Cooperation
- Chapter 2: Military and Security Issues Involving China
 - Section 1: Year in Review: Security and Foreign Affairs
 - Section 2: China's Military Modernization
 - Section 3: China's Domestic Stability
- Chapter 3: China and the World
 - Section 1: China and Asia's Evolving Security Architecture
 - Section 2: Recent Developments in China's Relationship with North Korea
 - Section 3: Taiwan
 - Section 4: Hong Kong

Location, Date and Time: Rayburn House Office Building, Room 2118. Thursday, November 20, 2014, 9:30 a.m. Eastern Time. Please check our Web site, www.uscc.gov, for possible changes to public meeting. *Reservations are not required to attend the hearing.*

FOR FURTHER INFORMATION CONTACT: Any member of the public seeking further information concerning the hearing should contact Reed Eckhold, 444 North Capitol Street NW., Suite 602, Washington, DC 20001; phone: 202-624-1496, or via email at reckhold@uscc.gov. *Reservations are not required to attend the hearing.*

Authority: Congress created the U.S.-China Economic and Security Review Commission in 2000 in the National Defense Authorization Act (Public Law 106-398), as amended by Division P of the Consolidated Appropriations Resolution, 2003 (Pub. L. 108-7), as amended by Public Law 109-108 (November 22, 2005).

Dated: November 7, 2014.

Michael Danis,
Executive Director, U.S.-China Economic and Security Review Commission.

[FR Doc. 2014-26892 Filed 11-12-14; 8:45 am]

BILLING CODE 1137-00-P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900-0778]

Agency Information Collection (Disability Benefits Questionnaires—Group 3) Activity Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before December 15, 2014.

ADDRESSES: Submit written comments on the collection of information through www.Regulations.gov, or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to oir_submission@omb.eop.gov. Please refer to “OMB Control No. 2900-0778” in any correspondence.

FOR FURTHER INFORMATION CONTACT: Crystal Rennie, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 632-7492 or email crystal.rennie@va.gov. Please refer to “OMB Control No. 2900-0778.”

SUPPLEMENTARY INFORMATION:

Titles:

- a. Central Nervous System and Neuromusculo Diseases, Disability Benefits Questionnaire, VA Form 21-0960C-5.
- b. Headaches (Including Migraine Headaches), Disability Benefits Questionnaire, VA Form 21-0960C-8.
- c. Multiple Sclerosis (MS), Disability Benefits Questionnaire, VA Form 21-0960C-9.
- d. Esophageal Disorders (Including GERD), Disability Benefits Questionnaire, VA Form 21-0960G-1.
- e. Gallbladder and Pancreas Conditions, Disability Benefits Questionnaire, VA Form 21-0960G-2.
- f. Intestinal Disorders (Other Than Surgical or Infectious) (Including Irritable Bowel Syndrome, Crohn's

Disease, Ulcerative Colitis, and Diverticulitis) Disability Benefits Questionnaire, VA Form 21-0960G-3.

g. Intestines Surgical and/or Infectious Intestinal Disorders (Bowel Resection, Colostomy, Ileostomy, Bacterial and Parasitic Infections) Disability Benefits Questionnaire, VA Form 21-0960G-4.

h. Hepatitis, Cirrhosis and Other Liver Conditions, Disability Benefits Questionnaire, VA Form 21-0960G-5.

i. Peritoneal Adhesions Disability Benefits Questionnaire, VA Form 21-0960G-6.

j. Stomach and Duodenal Conditions (Not Including GERD or Esophageal Disorders) Disability Benefits Questionnaire, VA Form 21-0960G-7.

k. Infectious Intestinal Disorders, Including Bacterial and Parasitic Infections Disability Benefits Questionnaire, VA Form 21-0960G-8.

l. Rectum and Anus Disability Benefits Questionnaire, VA Form 21-0960H-2.

m. Breast Conditions and Disorders Disability Benefits Questionnaire, VA Form 21-0960K-1.

n. Gynecological Conditions Disability Benefits Questionnaire, VA Form 21-0960K-2.

o. Sleep Apnea Disability Benefits Questionnaire, VA Form 21-0960L-2.

p. Osteomyelitis Disability Benefits Questionnaire, VA Form 21-0960M-11.

q. Ear Conditions (Including Vestibular and Infectious) Disability Benefits Questionnaire, VA Form 21-0960N-1.

OMB Control Number: 2900-0778.

Type of Review: Revised collection.

Abstract: Data collected on VA Form 21-0960 series will be used obtain

information from claimants treating physician that is necessary to adjudicate a claim for disability benefits.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on April 15, 2014, at pages 48296-48297.

Affected Public: Individuals or households.

Estimated Annual Burden:

- a. VA Form 21-0960C-5—5,000.
- b. VA Form 21-0960C-8—3,750.
- c. VA Form 21-0960C-9—7,500.
- d. VA Form 21-0960G-1—10,000.
- e. VA Form 21-0960G-2—1,250.
- f. VA Form 21-0960G-3—1,250.
- g. VA Form 21-0960G-4—1,250.
- h. VA Form 21-0960G-5—5,000.
- i. VA Form 21-0960G-6—1,250.
- j. VA Form 21-0960G-7—2,500.
- k. VA Form 21-0960G-8—1,250.
- l. VA Form 21-0960H-2—2,500.
- m. VA Form 21-0960K-1—7,500.
- n. VA Form 21-0960K-2—10,000.
- o. VA Form 21-0960L-2—1,250.
- p. VA Form 21-0960M-11—10,000.
- q. VA Form 21-0960N-1—6,250.

Estimated Average Burden per Respondent:

- a. VA Form 21-0960C-5—30 minutes.
- b. VA Form 21-0960C-8—15 minutes.
- c. VA Form 21-0960C-9—45 minutes.
- d. VA Form 21-0960G-1—15 minutes.
- e. VA Form 21-0960G-2—15 minutes.
- f. VA Form 21-0960G-3—15 minutes.
- g. VA Form 21-0960G-4—15 minutes.
- h. VA Form 21-0960G-5—30 minutes.

i. VA Form 21-0960G-6—15 minutes.

j. VA Form 21-0960G-7—15 minutes.

k. VA Form 21-0960G-8—15 minutes.

l. VA Form 21-0960H-2—15 minutes.

m. VA Form 21-0960K-1—15 minutes.

n. VA Form 21-0960K-2—30 minutes.

o. VA Form 21-0960L-2—15 minutes.

p. VA Form 21-0960M-11—15 minutes.

q. VA Form 21-0960N-1—15 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents:

- a. VA Form 21-0960C-5—10,000.
- b. VA Form 21-0960C-8—15,000.
- c. VA Form 21-0960C-9—10,000.
- d. VA Form 21-0960G-1—40,000.
- e. VA Form 21-0960G-2—5,000.
- f. VA Form 21-0960G-3—5,000.
- g. VA Form 21-0960G-4—5,000.
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- j. VA Form 21-0960G-7—10,000.
- k. VA Form 21-0960G-8—5,000.
- l. VA Form 21-0960H-2—10,000.
- m. VA Form 21-0960K-1—30,000.
- n. VA Form 21-0960K-2—20,000.
- o. VA Form 21-0960L-2—5,000.
- p. VA Form 21-0960M-11—40,000.
- q. VA Form 21-0960N-1—25,000.

Dated: November 6, 2014.

By direction of the Secretary.

Crystal Rennie,

Department, Clearance Officer, Department of Veterans Affairs.

[FR Doc. 2014-26767 Filed 11-12-14; 8:45 am]

BILLING CODE 8320-01-P



FEDERAL REGISTER

Vol. 79 Thursday,
No. 219 November 13, 2014

Book 2 of 2 Books

Pages 67547–68092

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 405, 410, et al.

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Parts 403, 405, 410, 411, 412, 413, 414, 425, 489, 495, and 498****[CMS-1612-FC]****RIN 0938-AS12****Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final rule with comment period.

SUMMARY: This major final rule with comment period addresses changes to the physician fee schedule, and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. See the Table of Contents for a listing of the specific issues addressed in this rule.

DATES: *Effective date:* The provisions of this final rule are effective on January 1, 2015, with the exception of amendments to parts 412, 413, and 495 which are effective October 31, 2014.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 30, 2014.

Compliance date: The compliance date for new data collection requirements in § 403.904(c)(8) is January 1, 2016.

ADDRESSES: In commenting, please refer to file code CMS-1612-FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to www.regulations.gov. Follow the instructions for “submitting a comment.”

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1612-FC, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1612-FC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT: Donta Henson, (410) 786-1947 for any physician payment issues not identified below.

Gail Addis, (410) 786-4522, for issues related to the refinement panel.

Chava Sheffield, (410) 786-2298, for issues related to practice expense methodology, impacts, the sustainable growth rate, conscious sedation, or conversion factors.

Kathy Kersell, (410) 786-2033, for issues related to direct practice expense inputs.

Jessica Bruton, (410) 786-5991, for issues related to potentially misvalued services or work RVUs.

Craig Dobyski, (410) 786-4584, for issues related to geographic practice cost indices or malpractice RVUs.

Ken Marsalek, (410) 786-4502, for issues related to telehealth services.

Pam West, (410) 786-2302, for issues related to conditions for therapists in private practice or therapy caps.

Ann Marshall, (410) 786-3059, for issues related to chronic care management.

Marianne Myers, (410) 786-5962, for issues related to ambulance extender provisions.

Amy Gruber, (410) 786-1542, for issues related to changes in geographic area designations for ambulance payment.

Anne Tayloe-Hauswald, (410) 786-4546, for issues related to clinical lab fee schedule.

Corinne Axelrod, (410) 786-5620, for issues related to Rural Health Clinics or Federally Qualified Health Centers.

Renee Mentnech, (410) 786-6692, for issues related to access to identifiable data for the Centers for Medicare & Medicaid models.

Marie Casey, (410) 786-7861 or Karen Reinhardt, (410) 786-0189, for issues related to local coverage determination process for clinical diagnostic laboratory tests.

Frederick Grabau, (410) 786-0206, for issues related to private contracting/opt-out.

David Walczak, (410) 786-4475, for issues related to payment policy for substitute physician billing arrangements (*locum tenens*).

Melissa Heesters, (410) 786-0618, for issues related to reports of payments or other transfers of value to covered recipients.

Alesia Hovatter, (410) 786-6861, for issues related to physician compare.

Christine Estella, (410) 786-0485, for issues related to the physician quality reporting system.

Alexandra Mugge, (410) 786-4457, for issues related to EHR incentive program.

Patrice Holtz, (410) 786-5663, for issues related to comprehensive primary care initiative.

Terri Postma, (410) 786-4169, for issues related to Medicare Shared Savings Program.

Kimberly Spalding Bush, (410) 786-3232, for issues related to value-based modifier and improvements to physician feedback.

Elizabeth Holland, (410) 786-1309, Medicare EHR Incentive Program (Medicare payment adjustments and hardship exceptions).

Elisabeth Myers (CMS), (410) 786-4751, Medicare EHR Incentive Program (Medicare payment adjustments and hardship exceptions).

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of

the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

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Acronyms

In addition, because of the many organizations and terms to which we refer by acronym in this final rule with comment period, we are listing these acronyms and their corresponding terms in alphabetical order below:

- AAA Abdominal aortic aneurysms
- ACO Accountable care organization
- AMA American Medical Association
- ASC Ambulatory surgical center
- ATA American Telehealth Association
- ATRA American Taxpayer Relief Act (Pub. L. 112-240)
- BBA Balanced Budget Act of 1997 (Pub. L. 105-33)
- BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106-113)
- CAD Coronary artery disease
- CAH Critical access hospital
- CBSA Core-Based Statistical Area
- CCM Chronic care management
- CEHRT Certified EHR technology
- CF Conversion factor
- CG-CAHPS Clinician and Group Consumer Assessment of Healthcare Providers and Systems
- CLFS Clinical Laboratory Fee Schedule
- CNM Certified nurse-midwife
- CP Clinical psychologist
- CPC Comprehensive Primary Care
- CPEP Clinical Practice Expert Panel
- CPT [Physicians] Current Procedural Terminology (*CPT codes, descriptions and other data only are copyright 2014 American Medical Association. All rights reserved.*)
- CQM Clinical quality measure
- CSW Clinical social worker
- CT Computed tomography
- CY Calendar year
- DFAR Defense Federal Acquisition Regulations
- DHS Designated health services
- DM Diabetes mellitus
- DSMT Diabetes self-management training
- eCQM Electronic clinical quality measures

- EHR Electronic health record
- E/M Evaluation and management
- EP Eligible professional
- eRx Electronic prescribing
- ESRD End-stage renal disease
- FAR Federal Acquisition Regulations
- FFS Fee-for-service
- FQHC Federally qualified health center
- FR Federal Register
- GAF Geographic adjustment factor
- GAO Government Accountability Office
- GPCI Geographic practice cost index
- GPO Group purchasing organization
- GPRO Group practice reporting option
- GTR Genetic Testing Registry
- HCPCS Healthcare Common Procedure Coding System
- HHS [Department of] Health and Human Services
- HOPD Hospital outpatient department
- HPSA Health professional shortage area
- IDTF Independent diagnostic testing facility
- IPPS Inpatient Prospective Payment System
- IQR Inpatient Quality Reporting
- ISO Insurance service office
- IWPUT Intensity of work per unit of time
- LCD Local coverage determination
- MA Medicare Advantage
- MAC Medicare Administrative Contractor
- MAP Measure Applications Partnership
- MAPCP Multi-payer Advanced Primary Care Practice
- MAV Measure application validity [process]
- MCP Monthly capitation payment
- MedPAC Medicare Payment Advisory Commission
- MEI Medicare Economic Index
- MFP Multi-Factor Productivity
- MIPPA Medicare Improvements for Patients and Providers Act (Pub. L. 110-275)
- MMA Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108-173, enacted on December 8, 2003)
- MP Malpractice
- MPPR Multiple procedure payment reduction
- MRA Magnetic resonance angiography
- MRI Magnetic resonance imaging
- MSA Metropolitan Statistical Areas
- MSPB Medicare Spending per Beneficiary
- MSSP Medicare Shared Savings Program
- MU Meaningful use
- NCD National coverage determination
- NCQDIS National Coalition of Quality Diagnostic Imaging Services
- NP Nurse practitioner
- NPI National Provider Identifier
- NPP Nonphysician practitioner
- NQS National Quality Strategy
- OACT CMS's Office of the Actuary
- OBRA '89 Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101-239)
- OBRA '90 Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508)
- OES Occupational Employment Statistics
- OMB Office of Management and Budget
- OPPS Outpatient prospective payment system
- OT Occupational therapy
- PA Physician assistant
- PAMA Protecting Access to Medicare Act of 2014 (Pub. L. 113-93)
- PC Professional component
- PCIP Primary Care Incentive Payment

PE Practice expense
 PE/HR Practice expense per hour
 PEAC Practice Expense Advisory Committee
 PECOS Provider Enrollment, Chain, and Ownership System
 PFS Physician Fee Schedule
 PLI Professional Liability Insurance
 PMA Premarket approval
 PQRS Physician Quality Reporting System
 PPIS Physician Practice Expense Information Survey
 PT Physical therapy
 PY Performance year
 QCDR Qualified clinical data registry
 QRUR Quality and Resources Use Report
 RBRVS Resource-based relative value scale
 RFA Regulatory Flexibility Act
 RHC Rural health clinic
 RIA Regulatory impact analysis
 RUC American Medical Association/ Specialty Society Relative (Value) Update Committee
 RUCA Rural Urban Commuting Area
 RVU Relative value unit
 SBA Small Business Administration
 SGR Sustainable growth rate
 SIM State Innovation Model
 SLP Speech-language pathology
 SMS Socioeconomic Monitoring System
 SNF Skilled nursing facility
 TAP Technical Advisory Panel
 TC Technical component
 TIN Tax identification number
 UAF Update adjustment factor
 UPIN Unique Physician Identification Number
 USPSTF United States Preventive Services Task Force
 VBP Value-based purchasing
 VM Value-Based Payment Modifier

Addenda Available Only Through the Internet on the CMS Web Site

The PFS Addenda along with other supporting documents and tables referenced in this final rule with comment period are available through the Internet on the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSchedule/PFS-Federal-Regulation-Notices.html>. Click on the link on the left side of the screen titled, "PFS Federal Regulations Notices" for a chronological list of PFS **Federal Register** and other related documents. For the CY 2015 PFS final rule with comment period, refer to item CMS–1612–FC. Readers who experience any problems accessing any of the Addenda or other documents referenced in this rule and posted on the CMS Web site identified above should contact donta.henson1@cms.hhs.gov.

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I. Executive Summary and Background

A. Executive Summary

1. Purpose

This major final rule with comment period revises payment policies under the Medicare Physician Fee Schedule (PFS) and makes other policy changes related to Medicare Part B payment. These changes are applicable to services furnished in CY 2015.

2. Summary of the Major Provisions

The Social Security Act (the Act) requires us to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The Act requires that RVUs be established for three categories of resources: Work, practice expense (PE); and malpractice (MP) expense; and, that we establish by regulation each year's payment amounts for all physicians' services, incorporating geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas. In this major final rule with comment period, we establish RVUs for CY 2015 for the PFS, and other Medicare Part B payment policies, to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. In addition, this final rule with comment period includes discussions and proposals regarding:

- Misvalued PFS Codes.
- Telehealth Services.
- Chronic Care Management Services.
- Establishing Values for New, Revised, and Misvalued Codes.
- Updating the Ambulance Fee Schedule regulations.
- Changes in Geographic Area Delineations for Ambulance Payment.
- Updating the—
 - ++ Physician Compare Web site.
 - ++ Physician Quality Reporting System.
 - ++ Medicare Shared Savings Program.
 - ++ Electronic Health Record (EHR) Incentive Program.
 - Value-Based Payment Modifier and the Physician Feedback Program.

3. Summary of Costs and Benefits

The Act requires that annual adjustments to PFS RVUs may not cause

annual estimated expenditures to differ by more than \$20 million from what they would have been had the adjustments not been made. If adjustments to RVUs would cause expenditures to change by more than \$20 million, we must make adjustments to preserve budget neutrality. These adjustments can affect the distribution of Medicare expenditures across specialties. In addition, several proposed changes would affect the specialty distribution of Medicare expenditures. When considering the combined impact of work, PE, and MP RVU changes, the projected payment impacts are small for most specialties; however, the impact would be larger for a few specialties.

We have determined that this final rule with comment period is economically significant. For a detailed discussion of the economic impacts, see section VII. of this final rule with comment period.

B. Background

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Act, "Payment for Physicians' Services." The system relies on national relative values that are established for work, PE, and MP, which are adjusted for geographic cost variations. These values are multiplied by a conversion factor (CF) to convert the RVUs into payment rates. The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239, enacted on December 19, 1989) (OBRA '89), and the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508, enacted on November 5, 1990) (OBRA '90). The final rule published on November 25, 1991 (56 FR 59502) set forth the first fee schedule used for payment for physicians' services.

We note that throughout this final rule with comment period, unless otherwise noted, the term "practitioner" is used to describe both physicians and nonphysician practitioners (NPPs) who are permitted to bill Medicare under the PFS for services furnished to Medicare beneficiaries.

1. Development of the Relative Values

a. Work RVUs

The work RVUs established for the initial fee schedule, which was implemented on January 1, 1992, were developed with extensive input from the physician community. A research team at the Harvard School of Public Health developed the original work RVUs for most codes under a

cooperative agreement with the Department of Health and Human Services (HHS). In constructing the code-specific vignettes used in determining the original physician work RVUs, Harvard worked with panels of experts, both inside and outside the federal government, and obtained input from numerous physician specialty groups.

As specified in section 1848(c)(1)(A) of the Act, the work component of physicians' services means the portion of the resources used in furnishing the service that reflects physician time and intensity. We establish work RVUs for new, revised and potentially misvalued codes based on our review of information that generally includes, but is not limited to, recommendations received from the American Medical Association/Specialty Society Relative Value Update Committee (RUC), the Health Care Professionals Advisory Committee (HCPAC), the Medicare Payment Advisory Commission (MedPAC), and other public commenters; medical literature and comparative databases; as well as a comparison of the work for other codes within the Medicare PFS, and consultation with other physicians and health care professionals within CMS and the federal government. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters, and the rationale for their recommendations.

b. Practice Expense RVUs

Initially, only the work RVUs were resource-based, and the PE and MP RVUs were based on average allowable charges. Section 121 of the Social Security Act Amendments of 1994 (Pub. L. 103-432, enacted on October 31, 1994), amended section 1848(c)(2)(C)(ii) of the Act and required us to develop resource-based PE RVUs for each physicians' service beginning in 1998. We were required to consider general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising PEs. The PE RVUs continue to represent the portion of these resources involved in furnishing PFS services.

Originally, the resource-based method was to be used beginning in 1998, but section 4505(a) of the Balanced Budget Act of 1997 (Pub. L. 105-33, enacted on August 5, 1997) (BBA) delayed implementation of the resource-based PE RVU system until January 1, 1999. In addition, section 4505(b) of the BBA provided for a 4-year transition period

from the charge-based PE RVUs to the resource-based PE RVUs.

We established the resource-based PE RVUs for each physicians' service in a final rule, published on November 2, 1998 (63 FR 58814), effective for services furnished in CY 1999. Based on the requirement to transition to a resource-based system for PE over a 4-year period, payment rates were not fully based upon resource-based PE RVUs until CY 2002. This resource-based system was based on two significant sources of actual PE data: The Clinical Practice Expert Panel (CPEP) data and the AMA's Socioeconomic Monitoring System (SMS) data. (These data sources are described in greater detail in the CY 2012 final rule with comment period (76 FR 73033).)

Separate PE RVUs are established for services furnished in facility settings, such as a hospital outpatient department (HOPD) or an ambulatory surgical center (ASC), and in nonfacility settings, such as a physician's office. The nonfacility RVUs reflect all of the direct and indirect PEs involved in furnishing a service described by a particular HCPCS code. The difference, if any, in these PE RVUs generally results in a higher payment in the nonfacility setting because in the facility settings some costs are borne by the facility. Medicare's payment to the facility (such as the outpatient prospective payment system (OPPS) payment to the HOPD) would reflect costs typically incurred by the facility. Thus, payment associated with those facility resources is not made under the PFS.

Section 212 of the Balanced Budget Refinement Act of 1999 (Pub. L. 106-113, enacted on November 29, 1999) (BBRA) directed the Secretary of Health and Human Services (the Secretary) to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. On May 3, 2000, we published the interim final rule (65 FR 25664) that set forth the criteria for the submission of these supplemental PE survey data. The criteria were modified in response to comments received, and published in the **Federal Register** (65 FR 65376) as part of a November 1, 2000 final rule. The PFS final rules published in 2001 and 2003, respectively, (66 FR 55246 and 68 FR 63196) extended the period during which we would accept these supplemental data through March 1, 2005.

In the CY 2007 PFS final rule with comment period (71 FR 69624), we revised the methodology for calculating direct PE RVUs from the top-down to the bottom-up methodology beginning in CY 2007. We adopted a 4-year transition to the new PE RVUs. This transition was completed for CY 2010. In the CY 2010 PFS final rule with comment period, we updated the practice expense per hour (PE/HR) data that are used in the calculation of PE RVUs for most specialties (74 FR 61749). In CY 2010, we began a 4-year transition to the new PE RVUs using the updated PE/HR data, which was completed for CY 2013.

c. Malpractice RVUs

Section 4505(f) of the BBA amended section 1848(c) of the Act to require that we implement resource-based MP RVUs for services furnished on or after CY 2000. The resource-based MP RVUs were implemented in the PFS final rule with comment period published November 2, 1999 (64 FR 59380). The MP RVUs are based on commercial and physician-owned insurers' malpractice insurance premium data from all the states, the District of Columbia, and Puerto Rico. For more information on MP RVUs, see section II.C. of this final rule with comment period.

d. Refinements to the RVUs

Section 1848(c)(2)(B)(i) of the Act requires that we review RVUs no less often than every 5 years. Prior to CY 2013, we conducted periodic reviews of work RVUs and PE RVUs independently. We completed five-year reviews of work RVUs that were effective for calendar years 1997, 2002, 2007, and 2012.

Although refinements to the direct PE inputs initially relied heavily on input from the RUC Practice Expense Advisory Committee (PEAC), the shifts to the bottom-up PE methodology in CY 2007 and to the use of the updated PE/HR data in CY 2010 have resulted in significant refinements to the PE RVUs in recent years.

In the CY 2012 PFS final rule with comment period (76 FR 73057), we finalized a proposal to consolidate reviews of work and PE RVUs under section 1848(c)(2)(B) of the Act and reviews of potentially misvalued codes under section 1848(c)(2)(K) of the Act into one annual process.

With regard to MP RVUs, we completed five-year reviews of MP that were effective in CY 2005 and CY 2010. This final rule with comment period establishes a five-year review for CY 2015.

In addition to the five-year reviews, beginning for CY 2009, CMS, and the RUC have identified and reviewed a number of potentially misvalued codes on an annual basis based on various identification screens. This annual review of work and PE RVUs for potentially misvalued codes was supplemented by the amendments to section 1848 of the Act, as enacted by section 3134 of the Affordable Care Act, which requires the agency to periodically identify, review and adjust values for potentially misvalued codes.

e. Application of Budget Neutrality To Adjustments of RVUs

As described in section VI.C. of this final rule with comment period, in accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if revisions to the RVUs caused expenditures for the year to change by more than \$20 million, we make adjustments to ensure that expenditures did not increase or decrease by more than \$20 million.

2. Calculation of Payments Based on RVUs

To calculate the payment for each physicians' service, the components of the fee schedule (work, PE, and MP RVUs) are adjusted by geographic practice cost indices (GPCIs) to reflect the variations in the costs of furnishing the services. The GPCIs reflect the relative costs of physician work, PE, and MP in an area compared to the national average costs for each component. (See section II.D. of this final rule with comment period for more information about GPCIs.)

RVUs are converted to dollar amounts through the application of a CF, which is calculated based on a statutory formula by CMS's Office of the Actuary (OACT). The CF for a given year is calculated using (a) the productivity-adjusted increase in the Medicare Economic Index (MEI) and (b) the Update Adjustment Factor (UAF), which is calculated by taking into account the Medicare Sustainable Growth Rate (SGR), an annual growth rate intended to control growth in aggregate Medicare expenditures for physicians' services, and the allowed and actual expenditures for physicians' services. The formula for calculating the Medicare fee schedule payment amount for a given service and fee schedule area can be expressed as:

$$\text{Payment} = [(\text{RVU work} \times \text{GPCI work}) + (\text{RVU PE} \times \text{GPCI PE}) + (\text{RVU MP} \times \text{GPCI MP})] \times \text{CF}.$$

3. Separate Fee Schedule Methodology for Anesthesia Services

Section 1848(b)(2)(B) of the Act specifies that the fee schedule amounts for anesthesia services are to be based on a uniform relative value guide, with appropriate adjustment of an anesthesia conversion factor, in a manner to assure that fee schedule amounts for anesthesia services are consistent with those for other services of comparable value. Therefore, there is a separate fee schedule methodology for anesthesia services. Specifically, we establish a separate conversion factor for anesthesia services and we utilize the uniform relative value guide, or base units, as well as time units, to calculate the fee schedule amounts for anesthesia services. Since anesthesia services are not valued using RVUs, a separate methodology for locality adjustments is also necessary. This involves an adjustment to the national anesthesia CF for each payment locality.

4. Most Recent Changes to the Fee Schedule

The CY 2014 PFS final rule with comment period (78 FR 74230) implemented changes to the PFS and other Medicare Part B payment policies. It also finalized many of the CY 2013 interim final RVUs and established interim final RVUs for new and revised codes for CY 2014 to ensure that our payment system is updated to reflect changes in medical practice, coding changes, and the relative values of services. It also implemented section 635 of the American Taxpayer Relief Act of 2012 (Pub. L. 112–240, enacted on January 2, 2013) (ATRA), which revised the equipment utilization rate assumption for advanced imaging services furnished on or after January 1, 2014.

Also, in the CY 2014 PFS final rule with comment period, we announced the following for CY 2014: the total PFS update of –20.1 percent; the initial estimate for the SGR of –16.7 percent; and a CF of \$27.2006. These figures were calculated based on the statutory provisions in effect on November 27, 2013, when the CY 2014 PFS final rule with comment period was issued.

The Pathway for SGR Reform Act of 2013 (Pub. L. 113–67, enacted on December 26, 2013) established a 0.5 percent update to the PFS CF through March 31, 2014 and the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93, enacted on April 1, 2014) (PAMA) extended this 0.5 percent update through December 31, 2014. As a result, the CF for CY 2014 that was published in the CY 2014 final rule with

comment period (78 FR 74230) was revised to \$35.8228 for services furnished on or after January 1, 2014 and on or before December 31, 2014. The PAMA provides for a 0.0 percent update to the PFS for services furnished on or after January 1, 2015 and on or before March 31, 2015.

The Pathway for SGR Reform Act extended through March 31, 2014 several provisions of Medicare law that would have otherwise expired on December 31, 2013. The PAMA extended these same provisions further through March 31, 2015. A list of these provisions follows.

- The 1.0 floor on the work geographic practice cost index
- The exceptions process for outpatient therapy caps
- The manual medical review process for therapy services
- The application of the therapy caps and related provisions to services furnished in HOPDs

In addition, section 220 of the PAMA included several provisions affecting the valuation process for services under the PFS. Section 220(a) of the PAMA amended section 1848(c)(2) of the Act to add a new subparagraph (M). The new subparagraph (M) provides that the Secretary may collect or obtain information from any eligible professional or any other source on the resources directly or indirectly related to furnishing services for which payment is made under the PFS, and that such information may be used in the determination of relative values for services under the PFS. Such information may include the time involved in furnishing services; the amounts, types and prices of practice expense inputs; overhead and accounting information for practices of physicians and other suppliers, and any other elements that would improve the valuation of services under the PFS. This information may be collected or obtained through surveys of physicians or other suppliers, providers of services, manufacturers, and vendors; surgical logs, billing systems, or other practice or facility records; EHRs; and any other mechanism determined appropriate by the Secretary. If we use this information, we are required to disclose the source and use of the information in rulemaking, and to make available aggregated information that does not disclose individual eligible professionals, group practices, or information obtained pursuant to a nondisclosure agreement. Beginning with fiscal year 2014, the Secretary may compensate eligible professionals for submission of data.

Section 220(c) of the PAMA amended section 1848(c)(2)(K)(ii) of the Act to expand the categories of services that the Secretary is directed to examine for the purpose of identifying potentially misvalued codes. The nine new categories are as follows:

- Codes that account for the majority of spending under the PFS.
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.
- Codes for which there may be a change in the typical site of service since the code was last valued.
- Codes for which there is a significant difference in payment for the same service between different sites of service.
- Codes for which there may be anomalies in relative values within a family of codes.
- Codes for services where there may be efficiencies when a service is furnished at the same time as other services.
- Codes with high intra-service work per unit of time.
- Codes with high PE RVUs.
- Codes with high cost supplies.

(See section II.B. of this final rule with comment period for more information about misvalued codes.).

Section 220(i) of the PAMA also requires the Secretary to make publicly available the information we considered when establishing the multiple procedure payment reduction (MPPR) policy for the professional component of advanced imaging procedures. The policy reduces the amount paid for the professional component when two advanced imaging procedures are furnished in the same session. The policy was effective for individual physicians on January 1, 2012 and for physicians in the same group practice on January 1, 2013.

In addition, section 220 of the PAMA includes other provisions regarding valuation of services under the PFS that take effect in future years. Section 220(d) of the PAMA establishes an annual target from CY 2017 through CY 2020 for reductions in PFS expenditures resulting from adjustments to relative values of misvalued services. The target is calculated as 0.5 percent of the estimated amount of expenditures under the fee schedule for the year. If the net reduction in expenditures for the year is equal to or greater than the target for the year, the funds shall be redistributed in a budget-neutral manner within the PFS. The amount by which such reduced expenditures exceed the target for the year shall be treated as a

reduction in expenditures for the subsequent year, for purposes of determining whether the target has or has not been met. The legislation includes an exemption from budget neutrality of reduced expenditures if the target is not met. Other provisions of section 220 of the PAMA include a 2-year phase-in for reductions in RVUs of at least 20 percent for potentially misvalued codes that do not involve coding changes, and certain adjustments to the fee schedule areas in California. These provisions will be addressed as we implement them in future rulemaking.

On March 5, 2014, we submitted to MedPAC an estimate of the SGR and CF applicable to Medicare payments for physicians' services for CY 2015, as required by section 1848(d)(1)(E) of the Act. The actual values used to compute physician payments for CY 2015 will be based on later data and are scheduled to be published by November 1, 2014, as part of the CY 2015 PFS final rule with comment period.

C. Health Information Technology

The Department of Health and Human Services (HHS) believes all patients, their families, and their health care providers should have consistent and timely access to patient health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the patient's care. (HHS August 2013 Statement, "Principles and Strategies for Accelerating Health Information Exchange," see http://www.healthit.gov/sites/default/files/acceleratinghieprinciples_strategy.pdf) HHS is committed to accelerating health information exchange (HIE) through the use of safe, interoperable health information technology (health IT), including electronic health records (EHRs), across the broader care continuum through a number of initiatives: (1) Alignment of incentives and payment adjustments to encourage provider adoption and optimization of health IT and HIE services through Medicare and Medicaid payment policies; (2) adoption of common standards and certification requirements for interoperable HIT; (3) support for privacy and security of patient information across all HIE-focused initiatives; and (4) governance of health information. These initiatives are designed to encourage HIE among health care providers, including professionals and hospitals eligible for the Medicare and Medicaid EHR Incentive Programs and those who are not eligible for the EHR Incentive Programs, and are designed to improve

care delivery and coordination across the entire care continuum. For example, the Transition of Care Measure #2 in Stage 2 of the Medicare and Medicaid EHR Incentive Programs requires HIE to share summary records for more than 10 percent of care transitions. In addition, to increase flexibility in the Office of the National Coordinator for Health Information Technology's (ONC) regulatory certification structure, ONC expressed in the 2014 Edition Release 2 final rule (79 FR 54472–73) an intent to propose future changes to the ONC HIT Certification Program that would permit more efficient certification of health IT for other health care settings, such as long-term and post-acute care and behavioral health settings.

We believe that health IT that incorporates usability features and has been certified to interoperable standards can effectively and efficiently help all providers improve internal care delivery practices, support management of patient care across the continuum, and support the reporting of electronically specified clinical quality measures (eCQMs).

II. Provisions of the Proposed Rule for PFS

A. Resource-Based Practice Expense (PE) Relative Value Units (RVUs)

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice expenses, as specified in section 1848(c)(1)(B) of the Act. As required by section 1848(c)(2)(C)(ii) of the Act, we use a resource-based system for determining PE RVUs for each physician's service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service-specific PE RVUs. We refer readers to the CY 2010 PFS final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the RUC and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the Five-Year Review of Work Relative Value Units under the PFS and Proposed Changes to the Practice Expense Methodology proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense Per Hour Data

We use survey data on indirect PEs incurred per hour worked in developing the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the practice expense per hour (PE/HR) by specialty that was obtained from the AMA's Socioeconomic Monitoring Surveys (SMS). The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Expense Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of both physicians and nonphysician practitioners (NPPs) paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare-recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology itself or the manner in which the PE/HR data are used in that methodology. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period from the previous

PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete for CY 2013. Therefore, PE RVUs from CY 2013 forward are developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs, nor independent labs, participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the MEI to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties currently are not separately recognized by Medicare, nor do we have a method to blend the PPIS data with Medicare-recognized specialty data.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS-based PE/HR. We continue previous crosswalks for specialties that did not participate in the PPIS. However, beginning in CY 2010 we changed the PE/HR crosswalk for portable x-ray suppliers from radiology to IDTF, a more appropriate crosswalk because these specialties are more similar to each other for work time.

For registered dietitian services, the resource-based PE RVUs have been calculated in accordance with the final policy that crosswalks the specialty to

the "All Physicians" PE/HR data, as adopted in the CY 2010 PFS final rule with comment period (74 FR 61752) and discussed in more detail in the CY 2011 PFS final rule with comment period (75 FR 73183).

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of \$400 from our PE database and another service has a direct cost sum of \$200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

Section II.A.2.b. of this final rule with comment period describes the current data sources for specialty-specific indirect costs used in our PE calculations. We allocated the indirect costs to the code level on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the physician work RVUs. We also incorporated the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. In other words, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represented 25 percent of total costs for the specialties that furnished the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in

a total PE RVUs of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).

- Next, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had work RVUs of 4.00 and the clinical labor portion of the direct PE RVUs was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.

- Next, we incorporate the specialty-specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

d. Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a hospital or other facility setting, we establish two PE RVUs: Facility and nonfacility. The methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs, but is applied independently to yield two separate PE RVUs. Because in calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service in a facility, the facility PE RVUs are generally lower than the nonfacility PE RVUs. Medicare makes a separate payment to the facility for its costs of furnishing a service.

e. Services With Technical Components (TCs) and Professional Components (PCs)

Diagnostic services are generally comprised of two components: A professional component (PC); and a technical component (TC). The PC and TC may be furnished independently or

by different providers, or they may be furnished together as a "global" service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global.)

f. PE RVU Methodology

For a more detailed description of the PE RVU methodology, we refer readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746).

(1) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty-specific PE/HR data calculated from the surveys.

(2) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service. Apply a scaling adjustment to the direct inputs.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. This is the product of the current aggregate PE (direct and indirect) RVUs, the CF, and the average direct PE percentage from the survey data used for calculating the PE/HR by specialty.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregated direct costs for all services from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3, calculate a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling factor to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to an RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs, as long as the same CF is used in Step 2 and Step 5. Different CFs will result in different direct PE scaling factors, but this has no effect on the final direct cost PE RVUs since changes in the CFs and

changes in the associated direct scaling factors offset one another.

(3) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: The direct PE RVUs; the clinical PE RVUs; and the work RVUs.

For most services the indirect allocator is: Indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: Indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs.

- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: Indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs.

(**Note:** For global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs will be allocated using the work RVUs, and for the TC service, indirect PEs will be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes in the examples in Table 1, the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).

- The second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying

the current aggregate pool of PE RVUs by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty-specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty-specific indirect PE/HR data, calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the work time for the service, and the specialty's

utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty-specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty-specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (Note: For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(4) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 6 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment. The final PE BN adjustment is calculated by comparing the results of Step 18 to the current pool of PE RVUs. This final BN adjustment is required to redistribute RVUs from step 18 to all PE RVUs in the PFS, and because certain specialties are excluded from the PE RVU calculation for ratesetting purposes, but we note that all specialties are included for purposes of calculating the final BN adjustment. (See "Specialties excluded from ratesetting calculation" later in this section.)

(5) Setup File Information

- *Specialties excluded from ratesetting calculation:* For the purposes of calculating the PE RVUs, we exclude certain specialties, such as certain nonphysician practitioners paid at a percentage of the PFS and low-volume specialties, from the calculation. These specialties are included for the purposes of calculating the BN adjustment. They are displayed in Table 1.

TABLE 1—SPECIALTIES EXCLUDED FROM RATESSETTING CALCULATION

Specialty code	Specialty description
49	Ambulatory surgical center.
50	Nurse practitioner.
51	Medical supply company with certified orthotist.
52	Medical supply company with certified prosthetist.
53	Medical supply company with certified prosthetist-orthotist.
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist.
56	Individual certified prosthetist.
57	Individual certified prosthetist-orthotist.
58	Medical supply company with registered pharmacist.
59	Ambulance service supplier, e.g., private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies.
61	Voluntary health or charitable agencies.
73	Mass immunization roster biller.
74	Radiation therapy centers.
87	All other suppliers (e.g., drug and department stores).
88	Unknown supplier/provider specialty.
89	Certified clinical nurse specialist.
96	Optician.
97	Physician assistant.
A0	Hospital.
A1	SNF.
A2	Intermediate care nursing facility.
A3	Nursing facility, other.
A4	HHA.
A5	Pharmacy.
A6	Medical supply company with respiratory therapist.
A7	Department store.
B2	Pedorthic personnel.
B3	Medical supply company with pedorthic personnel.

- *Crosswalk certain low volume physician specialties:* Crosswalk the utilization of certain specialties with

relatively low PFS utilization to the associated specialties.

- *Physical therapy utilization:* Crosswalk the utilization associated

with all physical therapy services to the specialty of physical therapy.

- *Identify professional and technical services not identified under the usual TC and 26 modifiers:* Flag the services that are PC and TC services, but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global

service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).

- *Payment modifiers:* Payment modifiers are accounted for in the creation of the file consistent with current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at

surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the work time file is used; where it is not present, the intraoperative percentage from the payment files used by contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time accordingly. Table 2 details the manner in which the modifiers are applied.

TABLE 2—APPLICATION OF PAYMENT MODIFIERS TO UTILIZATION FILES

Modifier	Description	Volume adjustment	Time adjustment
80,81,82 AS	Assistant at Surgery Assistant at Surgery—Physician Assistant.	16% 14% (85% * 16%)	Intraoperative portion. Intraoperative portion.
50 or LT and RT .. 51	Bilateral Surgery Multiple Procedure	150% 50%	150% of work time. Intraoperative portion.
52	Reduced Services	50%	50%.
53	Discontinued Procedure	50%	50%.
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims.	Preoperative + Intraoperative portion.
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims.	Postoperative portion.
62	Co-surgeons	62.5%	50%.
66	Team Surgeons	33%	33%.

We also make adjustments to volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPR). We note that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the BN calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These MPPRs are not included in the development of the RVUs.

For anesthesia services, we do not apply adjustments to volume since the average allowed charge is used when simulating RVUs, and therefore, includes all adjustments. A time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where time units are duplicative.

- *Work RVUs:* The setup file contains the work RVUs from this final rule with comment period.

(6) Equipment Cost Per Minute

The equipment cost per minute is calculated as:

$$(1/(\text{minutes per year} * \text{usage})) * \text{price} * ((\text{interest rate}/(1 - (1/(1 + \text{interest rate})^{\text{life of equipment}})))) + \text{maintenance})$$

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage = 1); generally 150,000 minutes.

usage = variable, see discussion below.

price = price of the particular piece of equipment.

life of equipment = useful life of the particular piece of equipment.

maintenance = factor for maintenance; 0.05.

interest rate = variable, see discussion below.

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by Section 1848(b)(4)(C) of the Act.

Maintenance: This factor for maintenance was proposed and finalized during rulemaking for CY 1998 PFS (62 FR 33164). Several stakeholders have suggested that this maintenance factor assumption should be variable. We solicited comments regarding reliable data on maintenance costs that vary for particular equipment items. We received several comments about variable maintenance costs, which we will consider in future rulemaking. We note, however, that we do not believe that high-level summary data from informal surveys constitutes reliable data. Rather than assertions that a

particular maintenance rate is typical, multiple invoices containing equipment prices that are accompanied by maintenance contracts would provide support for a maintenance cost other than our currently assumed 5 percent. We continue to seek reliable data about variable maintenance costs, as we consider adjustments to our methodology to accommodate variable maintenance costs.

Per-use Equipment Costs: Several stakeholders have also suggested that our PE methodology should incorporate usage fees and other per-use equipment costs as direct costs. We also solicited comment on adjusting our cost formula to include equipment costs that do not vary based on the equipment time. We received a comment that addressed how to incorporate usage fees and other per-use equipment costs into our methodology, and received several comments that addressed how we should reclassify the anomalous supply inputs removed from the direct PE database. We will consider these comments in future rulemaking, including the way these anomalous supply inputs fit in to any future proposals related to per-use costs.

Interest Rate: In the CY 2013 final rule with comment period (77 FR 68902), we updated the interest rates used in

developing an equipment cost per minute calculation. The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). The interest rates are listed

in Table 3. (See 77 FR 68902 for a thorough discussion of this issue.)

TABLE 3—SBA MAXIMUM INTEREST RATES

Price	Useful life	Interest rate (%)
<\$25K	<7 Years	7.50
\$25K to \$50K	<7 Years	6.50
>\$50K	<7 Years	5.50
<\$25K	7+ Years	8.00
\$25K to \$50K	7+ Years	7.00
>\$50K	7+ Years	6.00

TABLE 4—CALCULATION OF PE RVUS UNDER METHODOLOGY FOR SELECTED CODES

Factor (CF) (2nd part)	Step	Source	Formula	99213 Office visit, non-facility	33533 CABG, arterial, single facility	71020 Chest x-ray non-facility	71020-TC Chest x-ray non-facility	71020-26 Chest x-ray, non-facility	93000 ECG, Complete, non-facility	93005 ECG, Tracing non-facility	93010 ECG, Report non-facility
(1) Labor cost (Lab)	Step 1	AMA	13.32	77.52	5.74	5.74	5.10	5.10
(2) Supply cost (Sup)	Step 1	AMA	2.98	7.34	0.53	0.53	1.19	1.19
(3) Equipment cost (Eqp)	Step 1	AMA	0.17	0.58	6.92	6.92	0.09	0.09
(4) Direct cost (Dir)	Step 1	AMA	$= (1) + (2) + (3)$	16.48	85.45	13.19	13.19	6.38	6.38
(5) Direct adjustment (Dir. Adj.)	Steps 2-4	See footnote*	0.5898	0.5898	0.5898	0.5898	0.5898	0.5898	0.5898	0.5898
(6) Adjusted Labor	Steps 2-4	=Labor * Dir Adj	$= (1) * (5)$	7.86	45.72	3.39	3.39	3.01	3.01
(7) Adjusted Supplies	Steps 2-4	=Eqp * Dir Adj	$= (2) * (5)$	1.76	4.33	0.31	0.31	0.70	0.70
(8) Adjusted Equipment	Steps 2-4	=Sup * Dir Adj	$= (3) * (5)$	0.10	0.34	4.08	4.08	0.05	0.05
(9) Adjusted Direct	Steps 2-4	$= (6) + (7) + (8)$	9.72	50.40	7.78	7.78	3.77	3.77
(10) Conversion Factor (CF)	Step 5	PFS	35.82	35.82	35.82	35.82	35.82	35.82	35.82	35.82
(11) Adj. labor cost converted- ..	Step 5	$= (\text{Lab} * \text{Dir Adj}) / \text{CF}$	$= (6) / (10)$	0.22	1.28	0.09	0.09	0.08	0.08
(12) Adj. supply cost converted	Step 5	$= (\text{Sup} * \text{Dir Adj}) / \text{CF}$	$= (7) / (10)$	0.05	0.12	0.01	0.01	0.02	0.02
(13) Adj. equipment cost converted.	Step 5	$= (\text{Eqp} * \text{Dir Adj}) / \text{CF}$	$= (8) / (10)$	0.01	0.11	0.11
(14) Adj. direct cost converted ..	Step 5	$= (11) + (12) + (13)$	0.27	1.41	0.22	0.22	0.11	0.11
(15) Work RVU	Setup File	PFS	0.97	33.75	0.22	0.22	0.22	0.17	0.17	0.17
(16) Dir_pct	Steps 6,7	Surveys	0.25	0.17	0.29	0.29	0.29	0.29	0.29	0.29
(17) Ind_pct	Steps 6,7	Surveys	0.75	0.83	0.71	0.71	0.71	0.71	0.71	0.71
(18) Ind. Alloc. Formula (1st part).	Step 8	See Step 8	$((14) / (16)) * (17)$	$((14) / (16)) * (17)$	$((14) / (16)) * (17)$	$((14) / (16)) * (17)$	$((14) / (16)) * (17)$	$((14) / (16)) * (17)$	$((14) / (16)) * (17)$	$((14) / (16)) * (17)$
(19) Ind. Alloc.(1st part)	Step 8	See 18	0.82	6.67	0.53	0.53	0.26	0.26
(20) Ind. Alloc. Formula (2nd part).	Step 8	See Step 8	(15)	(15)	(15+11)	(11)	(15)	(15+11)	(11)	(15)
(21) Ind. Alloc.(2nd part)	Step 8	See 20	0.97	33.75	0.31	0.09	0.22	0.25	0.08	0.17
(22) Indirect Allocator (1st + 2nd).	Step 8	$= (19) + (21)$	1.79	40.42	0.84	0.62	0.22	0.51	0.34	0.17
(23) Indirect Adjustment (Ind. Adj.).	Steps 9-11	See Footnote**	0.3813	0.3813	0.3813	0.3813	0.3813	0.3813	0.3813	0.3813
(24) Adjusted Indirect Allocator	Steps 9-11	$= \text{Ind Alloc} * \text{Ind Adj}$	0.68	15.41	0.32	0.24	0.08	0.20	0.13	0.06
(25) Ind. Practice Cost Index (PCI).	Steps 12-16	1.07	0.75	0.99	0.99	0.99	0.91	0.91	0.91
(26) Adjusted Indirect	Step 17	$= \text{Adj. Ind Alloc} * \text{PCI}$	$= (24) * (25)$	0.73	11.59	0.32	0.24	0.08	0.18	0.12	0.06
(27) Final PE RVU	Step 18	$= (\text{Adj Dir} + \text{Adj Ind}) * \text{Other Adj}$	$= ((14) + (26)) * \text{Other Adj}$	1.01	13.04	0.54	0.46	0.08	0.29	0.23	0.06

Note: PE RVUs in Table 5, row 27, may not match Addendum B due to rounding.

*The indirect adj = [current pe rvus * CF * avg dir pct]/[sum direct inputs] = [step2]/[step3].

**The indirect adj = [current pe rvus * avg ind pct]/[sum of ind allocators] = [step9]/[step10].

Note: The use of any particular conversion factor (CF) in Table 5 to illustrate the PE Calculation has no effect on the resulting RVUs.

Note: The Other Adjustment includes an adjustment for the equipment utilization change.

3. Changes to Direct PE Inputs for Specific Services

In this section, we discuss other CY 2015 revisions related to direct PE inputs for specific services. The final direct PE inputs are included in the final rule CY 2015 direct PE input database, which is available on the CMS Web site under downloads for the CY 2015 PFS final rule with comment period at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/>

PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

a. RUC Recommendation for Monitoring Time following Moderate Sedation

We received a recommendation from the RUC regarding appropriate clinical labor minutes for post-procedure moderate sedation monitoring and post-procedure monitoring. The RUC recommended 15 minutes of RN time for one hour of monitoring following

moderate sedation and 15 minutes of RN time per hour for post-procedure monitoring (unrelated to moderate sedation). For 17 procedures listed in Table 5, the recommended clinical labor minutes differed from the clinical labor minutes in the direct PE database. We proposed to accept, without refinement, the RUC recommendation to adjust these clinical labor minutes as indicated in Table 5 as “Change to Clinical Labor Time.”

TABLE 5—CODES WITH CHANGES TO POST-PROCEDURE CLINICAL LABOR MONITORING TIME

CPT Code	Current monitoring time (min)	RUC recommended total post-procedure monitoring time (min)	Change to clinical labor time (min)
32553	30	60	30
35471	21	60	39
35475	60	30	–30
35476	60	30	–30
36147	18	30	12
37191	60	30	–30
47525	6	15	9
49411	30	60	30
50593	30	60	30
50200	15	60	45
31625	20	15	–5
31626	25	15	–10
31628	25	15	–10
31629	25	15	–10
31634	25	15	–10
31645	10	15	5
31646	10	15	5

Comment: We received two comments supporting our proposal to accept the RUC recommendation, without refinement, to adjust the clinical labor minutes as indicated in Table 5. One commenter noted that the RUC recommendation was a more accurate reflection of the monitoring time, particularly for codes 50593 (Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy) and 50200 (Renal biopsy; percutaneous, by trocar or needle), than the current time.

Response: We appreciate commenters’ support for our proposal. After consideration of comments received, we are finalizing our proposal to accept, without refinement, the RUC recommendation to adjust the clinical labor minutes as indicated in Table 5 as “Change to Clinical Labor Time.”

b. RUC Recommendation for Standard Moderate Sedation Package

We received a RUC recommendation to modify PE inputs included in the standard moderate sedation package. Specifically, the RUC indicated that several specialty societies have pointed to the need for a stretcher during

procedures for which moderate sedation is inherent in the procedure. Although the RUC did not recommend that we make changes to PE inputs for codes at this time, the RUC indicated that its future recommendations would include the stretcher as a direct input for procedures including moderate sedation.

The RUC recommended three scenarios that it would use in the future to allocate the equipment time for the stretcher based on the procedure time and whether the stretcher would be available for other patients to use during a portion of the procedure. Although we appreciate the RUC’s attention to the differences in the time required for the stretcher based on the time for the procedure, we believe that one of the purposes of standard PE input packages is to reduce the complexity associated with assigning appropriate PE inputs to individual procedures while, at the same time, maintaining relativity between procedures. Since we generally allocate inexpensive equipment items to the entire service period when they are likely to be unavailable for another use during the full service period, we

believe it is preferable to treat the stretcher consistently across services. Therefore, we proposed to modify the standard moderate sedation input package to include a stretcher for the same length of time as the other equipment items in the moderate sedation package. The revised moderate sedation input package will be applied to relevant codes as we review them through future notice and comment rulemaking. In seeking comments on the proposal, we stated that it would be useful to hear stakeholders’ views and the reasoning behind them on this issue, especially from those who think that the stretcher, as expressed through the allocation of equipment minutes, should be allocated with more granularity than the equipment costs that are allocated to other similar items.

Comment: We received comments supporting our proposal to add the stretcher to the moderate sedation package, including support to include the stretcher for the same length of time as the other equipment items included in the moderate sedation package since it is used by the patient for the duration

of their recovery and not available to other patients during that time.

Response: We appreciate the commenters' support for our proposal. After consideration of comments received, we are finalizing our proposal to add the stretcher to the moderate sedation package for the same length of time as the other equipment items in the moderate sedation package. We note that we will not apply this change retroactively, but will make the change to the moderate sedation package for codes being finalized for 2015, as well as interim final codes for 2015. For a detailed discussion of the specific codes impacted by this change, we refer readers to sections II.F. of this final rule with comment period.

c. RUC Recommendation for Migration From Film to Digital Practice Expense Inputs

The RUC provided a recommendation regarding the PE inputs for digital imaging services. Specifically, the RUC recommended that we remove a list of supply and equipment items associated with film technology since these items are no longer a typical resource input; these items are detailed in Table 6. The RUC also recommended that the Picture Archiving and Communication System (PACS) equipment be included for these imaging services since these items are now typically used in furnishing imaging services. We received a description of the PACS system as part of the recommendation, which included both items that appear to be direct PE items and items for which indirect PE RVUs are allocated in the PE methodology. As we have previously indicated, items which are not clinical labor, medical supplies, or medical equipment, or are not individually allocable to a particular patient for a particular procedure, are not categorized as direct costs in the PE methodology. Since we did not receive any invoices for the PACS system prior to the proposed rule, we were unable to determine the appropriate pricing to use for the inputs. We proposed to accept the RUC recommendation to remove the film supply and equipment items, and to allocate minutes for a desktop computer (ED021) as a proxy for the PACS workstation as a direct expense. Specifically, for the 31 services that already contain ED021 (computer, desktop, w-monitor), we proposed to retain the time that is currently included in the direct PE input database. For the remaining services that are valued in the nonfacility setting, we proposed to allocate the full clinical labor intraservice time to ED021, except for codes without clinical labor, in

which case we proposed to allocate the intraservice work time to ED021. For services valued only in the facility setting, we proposed to allocate the post-service clinical labor time to ED021, since the film supply and/or equipment inputs were previously associated with the post-service period.

TABLE 6—RUC-RECOMMENDED SUPPLY AND EQUIPMENT ITEMS REMOVED FOR DIGITAL IMAGING SERVICES

CMS Code	Description
SK013	computer media, dvd.
SK014	computer media, floppy disk 1.44mb.
SK015	computer media, optical disk 128mb.
SK016	computer media, optical disk 2.6gb.
SK022	film, 8inx10in (ultrasound, MRI).
SK025	film, dry, radiographic, 8in x 10in.
SK028	film, fluoroscopic 14 x 17.
SK033	film, x-ray 10in x 12in.
SK034	film, x-ray 14in x 17in.
SK035	film, x-ray 14in x 36in.
SK037	film, x-ray 8in x 10in.
SK038	film, x-ray 8in x 10in (X-omat, Radiomat).
SK086	video tape, VHS.
SK089	x-ray developer solution.
SK090	x-ray digitalization separator sheet.
SK091	x-ray envelope.
SK092	x-ray fixer solution.
SK093	x-ray ID card (flashcard).
SK094	x-ray marking pencil.
SK098	film, x-ray, laser print.
SM009	cleaner, x-ray cassette-screen.
ED014	computer workstation, 3D reconstruction CT-MR.
ED016	computer workstation, MRA post processing.
ED023	film processor, PET imaging.
ED024	film processor, dry, laser.
ED025	film processor, wet.
ED027	film processor, x-omat (M6B).
ER018	densitometer, film.
ER029	film alternator (motorized film viewbox).
ER067	x-ray view box, 4 panel.

We note that the RUC exempted certain procedures from its recommendation because (a) the dominant specialty indicated that digital technology is not yet typical or (b) the procedure only contained a single input associated with film technology, and it was determined that the sharing of images, but not actual imaging, may be involved in the service. However, we do not believe that the most appropriate approach in establishing relative values for services that involve imaging is to exempt services from the transition from film to digital PE inputs based on information reported by individual specialties. Although we understand that the migration from film technology to digital technology may progress at

different paces for particular specialties, we do not have information to suggest that the migration is not occurring for all procedures that require the storage of images. Just as it was appropriate to use film inputs as a proxy for some services for which digital inputs were typical pending these changes in the direct PE input database, we believe it is appropriate to use digital inputs as a proxy for the services that may still use film, pending their migration to digital technology. In addition, since the RUC conducted its collection of information from the specialties over several years, we believe the migration process from film to digital inputs has likely continued over the time period during which the information was gathered, and that the digital PE inputs will reflect typical use of technology for most if not all of these services before the change to digital inputs would take effect beginning January 1, 2015.

We noted that we believed that, for the sake of relativity, we should remove the equipment and supply inputs noted below from all procedures in the direct PE database, including those listed in Table 7. We sought comment on whether the computer workstation, which we proposed to use as a proxy for the PACS workstation, is the appropriate input for the services listed in Table 7, or whether an alternative input is a more appropriate reflection of direct PE costs.

TABLE 7—CODES CONTAINING FILM INPUTS BUT EXCLUDED FROM THE RUC RECOMMENDATION

HCPSCS	Short descriptor
21077	Prepare face/oral prosthesis.
28293	Correction of bunion.
61580	Craniofacial approach skull.
61581	Craniofacial approach skull.
61582	Craniofacial approach skull.
61583	Craniofacial approach skull.
61584	Orbitocranial approach/skull.
61585	Orbitocranial approach/skull.
61586	Resect nasopharynx skull.
64517	N block inj hypogas plxs.
64681	Injection treatment of nerve.
70310	X-ray exam of teeth.
77326	Brachytx isodose calc simp.
77327	Brachytx isodose calc interm.
77328	Brachytx isodose plan compl.
91010	Esophagus motility study.
91020	Gastric motility studies.
91034	Gastroesophageal reflux test.
91035	G-esoph reflx tst w/electrod.
91037	Esoph impeded function test.
91038	Esoph impeded funct test > 1hr.
91040	Esoph balloon distension tst.
91120	Rectal sensation test.
91122	Anal pressure record.
91132	Electrogastrography.
91133	Electrogastrography w/test.
92521	Evaluation of speech fluency.

TABLE 7—CODES CONTAINING FILM INPUTS BUT EXCLUDED FROM THE RUC RECOMMENDATION—Continued

HCPSCS	Short descriptor
92523	Speech sound lang comprehend.
92524	Behavioral qualitat analys voice.
92601	Cochlear implt f/up exam <7.
92603	Cochlear implt f/up exam 7/>.
92611	Motion fluoroscopy/swallow.
92612	Endoscopy swallow tst (fees).
92614	Laryngoscopic sensory test.
92616	Fees w/laryngeal sense test.
95800	Slp stdy unattended.
95801	Slp stdy unatnd w/anal.
95803	Actigraphy testing.
95805	Multiple sleep latency test.
95806	Sleep study unatt&resp efft.
95807	Sleep study attended.
95808	Polysom any age 1–3> param.
95810	Polysom 6/> yrs 4/> param.
95811	Polysom 6/>yrs cpap 4/> parm.
95812	Eeg 41–60 minutes.
95813	Eeg over 1 hour.
95829	Surgery electrocorticogram.
95950	Ambulatory eeg monitoring.
95953	Eeg monitoring/computer.
95954	Eeg monitoring/giving drugs.
95955	Eeg during surgery.
95956	Eeg monitor technol attended.
95957	Eeg digital analysis.
96904	Whole body photography.
G0270	Mnt subs tx for change dx.
G0271	Group mnt 2 or more 30 mins.

Finally, we noted that the RUC recommendation also indicated that, given the labor-intensive nature of reviewing all clinical labor tasks associated with film technology, these times would be addressed as these codes are reviewed. We agreed with the RUC that reviewing and adjusting the times for each code would be difficult and labor-intensive since the direct PE input database does not allow for a comprehensive adjustment of the clinical labor time based on changes in particular clinical labor tasks. To make broad adjustments such as this across codes, the PE database would need to contain the time associated with individual clinical labor tasks rather than reflecting only the sum of times for the pre-service period, service period, and post-service period, as it does now. We recognized this situation presents a challenge in implementing RUC recommendations such as this one, and makes it difficult to understand the basis of both the RUC's recommended clinical labor times and our refinements of those recommendations. Therefore, we stated that we were considering revising the direct PE input database to include task-level clinical labor time information for every code in the database. As an example, we referred readers to the supporting data files for

the direct PE inputs, which include public use files that display clinical labor times as allocated to each individual clinical labor task for a sample of procedures. We displayed this information as we attempt to increase the transparency of the direct PE database. We stated that we hoped that this modification would enable us to more accurately allocate equipment minutes to clinical labor tasks in a more consistent and efficient manner. Given the number of procedures and the volume of information involved, we sought comments on the feasibility of this approach. We note that we did not propose to make any changes to PE inputs for CY 2015 based on this modification to the design of the direct PE input database.

As discussed in section II.G. of this final rule with comment period, some of the RUC recommendations for 2015 included film items as practice expense inputs. For existing codes, the database from the proposed rule already included the PACS workstation proxy. However, for new services, as with the current items in the database, we have replaced the film items with the PACS workstation proxy. The codes affected by this change are listed in Table 8.

TABLE 8—CODES AFFECTED BY REMOVAL OF FILM INPUTS

HCPSCS	Short descriptor
22510	Perq cervicothoracic inject.
22511	Perq lumbosacral injection.
22513	Perq vertebral augmentation.
22514	Perq vertebral augmentation.
62302	Myelography lumbar injection.
62303	Myelography lumbar injection.
62304	Myelography lumbar injection.
62305	Myelography lumbar injection.
71275	Ct angiography chest.
72191	Ct angiograph pelv w/o&w/dye.
72240	Myelography neck spine.
72255	Myelography thoracic spine.
72265	Myelography l-s spine.
72270	Myelography 2/> spine regions.
74174	Ct angio abd&pelv w/o&w/dye.
74175	Ct angio abdom w/o & w/dye.
74230	Cine/vid x-ray throat/esoph.
76942	Echo guide for biopsy.
93312	Echo transesophageal.
93314	Echo transesophageal.
93320	Doppler echo exam heart.
93321	Doppler echo exam heart.
93325	Doppler color flow add-on.
93880	Extracranial bilat study.
93882	Extracranial uni/ltd study.
93886	Intracranial complete study.
93888	Intracranial limited study.
93895	Carotid intima atheroma eval.
93925	Lower extremity study.
93926	Lower extremity study.
93930	Upper extremity study.
93931	Upper extremity study.
93970	Extremity study.
93971	Extremity study.

TABLE 8—CODES AFFECTED BY REMOVAL OF FILM INPUTS—Continued

HCPSCS	Short descriptor
93975	Vascular study.
93976	Vascular study.
93978	Vascular study.
93979	Vascular study.

Comment: We received many comments on our proposal to remove the equipment and supply inputs associated with film technology from the direct PE database. In general, commenters supported our proposal to remove the film inputs from the direct PE database. Some commenters supported our use of the desktop computer as a proxy for the PACS workstation, but other commenters opposed using this item as a proxy. Commenters opposed to using the desktop computer as the proxy item stated that the PACS workstation was significantly more expensive and included greater functionality than a desktop computer. Some commenters opposed our proposal to maintain the current equipment time allocated to the computer desktop for the 31 services that already included this equipment item, suggesting that it was incorrect to eliminate the film inputs without proportionately increasing the proxy time for ED021. Some commenters requested a delay in implementation until stakeholders provide invoices or otherwise work with CMS to identify prices for the PACS items. Some commenters suggested CMS should develop a means to allocate digital technology costs to individual services, even if it is difficult to do so. Another commenter explained that it is difficult for stakeholders to obtain invoices that display prices for individual items, such as the PACS workstation, since the price of the particular items is often bundled with other related equipment and services. Many commenters urged CMS to work with stakeholders to obtain invoices, while other commenters requested that CMS accept the RUC recommendation regarding the PACS workstation.

Response: We appreciate commenters' support for our proposal to incorporate the transition from film to digital imaging technology into the direct PE input database. With regard to the pricing of the PACS workstation, as with all inputs, we would prefer to use actual paid invoices to establish the input price. However, in the absence of invoices demonstrating the actual cost, we believe that use of a proxy to price the appropriate inputs, in this case the PACS workstation, is preferable to

continuing to use inputs that we know are no longer typical. We made the proposal to use the computer, desktop, w-monitor (ED021), priced at \$2,501, as a proxy based on our assessment of similar resource costs between the item and the PACS workstation. Although some commenters stated that the item was not an appropriate proxy, these commenters did not provide any evidence to indicate that the resource costs are not similar or to suggest a more appropriate proxy. Nor were any paid invoices submitted. Absent such information, we continue to believe that using the proxy item is the best approach to incorporate the direct PE cost of the digital imaging technology.

With regard to the 31 services that already included the desktop computer as an equipment input, we will include the desktop computer as a proxy for the PACS workstation using the same methodology as for the services that did not previously contain the desktop computer. To clearly differentiate the desktop computer proxy from the desktop computer currently included in these services, and to facilitate accurate replacement of this input when we do receive pricing information, we will create a new equipment item called “desktop computer (proxy for PACS workstation),” which will be allocated to each procedure using the methodology described above.

Comment: Some commenters opposed our removal of the film inputs from services that were not included in the RUC recommendation, but did not provide a rationale for their opposition.

Response: For the reasons we explained in making the proposal and reiterate above, we continue to believe that it is appropriate to remove these items from the direct PE database.

Comment: Some commenters provided specific suggestions regarding the use of digital inputs should CMS decide to move forward with the proposal. Commenters requested that for portable x-ray services, CMS include a flat plate receptor/image capture plate to capture the image, specialized software to process the image, and multiple high definition monitors used by the interpreting radiologist. Commenters provided an invoice for the image capture plate at a price of \$25,600 indicating that this item replaces the film as the media to record the image.

Response: We appreciate that commenters provided us with an invoice for the image capture plate. However, services furnished by portable x-ray providers are reported using the same procedure codes as services provided using fixed machines. Since the typical x-ray service is furnished

using fixed equipment, we are not including the image capture plate that is associated with portable equipment as an input for the imaging procedure codes. We also do not believe that high definition monitors used by the interpreting radiologist are appropriately included in the technical component of imaging procedures; rather, these are indirect costs associated with the professional component of the service. Therefore, we are not including the high definition monitors as an input for these services. Finally, to determine whether the software is appropriately categorized as a direct PE input, we need more information about the functionality of the software, and whether it is used in furnishing the typical x-ray service (including services furnished using fixed machinery). Until we have information that supports the inclusion of this item as a direct cost, we will not include the software for x-ray services.

Comment: Commenters were supportive of the increased transparency with regard to the direct PE inputs, but several commenters suggested that there may be more feasible approaches to break out the individual clinical labor tasks associated with each portion of the service (pre-service period, service period, and post-service period). The RUC suggested that we post all PE worksheets and supporting materials in code-order on our Web site. Other commenters did not suggest a specific alternative approach to providing detail for the individual clinical labor tasks.

Response: We appreciate the RUC’s suggestion regarding the posting of the PE worksheets, but we do not believe that this would enable us to accomplish a comprehensive cross-code analysis and refinement to clinical labor times within the direct PE input database to increase consistency for identical clinical labor tasks between codes. Since we did not receive other suggestions from commenters on an approach to break out the individual clinical labor tasks associated with each service period to enable us to conduct the necessary analysis, we will pursue the approach described in the proposed rule. We will consider the comments submitted and continue to work with interested stakeholders regarding the best approaches to displaying the supporting files. We note that public use files continue to be available in the same format as in previous years, but that additional public use files now display the clinical labor tasks for each service period, providing greater transparency and enabling comparisons across codes. We note that we have

refined the file structure based on comments, and we continue to seek input on whether there are additional or alternative ways to display this information to enhance its clarity, and note that there are challenges inherent in the display of this information in a two-dimensional format. We refer readers to the public use files available on the CMS Web site under downloads for the CY 2015 PFS final rule with comment period at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>

d. Inputs for Digital Mammography Services

Mammography services are currently reported and paid using both CPT codes and G-codes. To meet the requirements of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), we established G-codes for use beginning in CY 2002 to pay for mammography services using new digital technologies (G0202 screening mammography digital; G0204 diagnostic mammography digital; G0206 diagnostic mammography digital). We continued to use the CPT codes for mammography services furnished using film technology (77055 (Mammography; unilateral); 77056 (Mammography; bilateral); 77057 (Screening mammography, bilateral (2-view film study of each breast))). As we discussed previously in this section, the RUC has recommended that all imaging codes, including mammography, be valued using digital rather than film inputs because the use of film is no longer typical. A review of Medicare claims data shows that the mammography CPT codes are billed extremely infrequently, and that the G-codes are billed for the vast majority of mammography claims, confirming the RUC’s conclusion that the typical service uses digital technology. As such, we stated that we do not believe there is a reason to continue the separate CPT codes and G-codes for mammography services since both sets of codes would have the same values when priced based upon the typical digital technology. Accordingly, we proposed to delete the mammography G-codes beginning for CY 2015 and to pay all mammography using the CPT codes.

We indicated that, although we believed that the CPT codes should now be used to report all mammography services, we had concerns about whether the current values for the CPT codes accurately reflect the resource inputs associated with furnishing the services. Because the CPT codes have not been recently reviewed and

significant technological changes have occurred since the current values were established, we did not believe it would be appropriate to retain the current values for the CPT codes. Therefore, we proposed to value the CPT codes using the RVUs previously established for the G-codes. We believed these values would be most appropriate since they were established to reflect the use of digital technology, which is now typical.

As discussed in section II.B of this final rule with comment period, we proposed these CPT codes as potentially misvalued and requested that the RUC and other interested stakeholders review these services in terms of appropriate work RVUs, work time assumptions, and direct PE inputs. However, as discussed in section II.B. of this final rule with comment period, we will continue to maintain separate payment rates for film and digital mammography while we consider revaluation of all mammography services. For CY 2015, we will therefore maintain both the G-codes and CPT codes; we will continue using the 2014 RVUs from each of the following codes to price them for 2015: G0202, G0204, G0206, 77055, 77056, and 77057. 2015. We also note that we will continue to pay for film mammography services at the 2014 rates until we revalue the mammography services.

We refer readers to section II.B. of this final rule with comment period, where we address comments received on this proposal.

e. Radiation Treatment Vault

In previous rulemaking (77 FR 68922, 78 FR 74346), we indicated that we included the radiation treatment vault as a direct PE input for several recently reviewed radiation treatment codes for the sake of consistency with its previous inclusion as a direct PE input for some other radiation treatment services, but that we intended to review the radiation treatment vault input and address whether or not it should be included in the direct PE input database for all services in future rulemaking. Specifically, we questioned whether it was consistent with the principles underlying the PE methodology to include the radiation treatment vault as a direct cost given that it appears to be more similar to building infrastructure costs than to medical equipment costs. In response to this discussion, we received comments and invoices from stakeholders who indicated that the vault should be classified as a direct cost. However, upon review of the information received, we believed that the specific structural components

required to house the linear accelerator are similar in concept to components required to house other medical equipment such as expensive imaging equipment. In general, the electrical, plumbing, and other building specifications are often unique to the intended functionality of a given building, including costs that are attributable to the specific medical equipment housed in the building, but those building characteristics do not represent direct medical equipment costs in our established PE methodology. Therefore, we believed that the special building requirements indicated for the radiation treatment vault to house a linear accelerator do not represent a direct cost in our PE methodology, and that the vault construction is instead accounted for in the indirect PE methodology, just as the building and infrastructure costs are treated for other PFS services including those with specialized infrastructure costs to accommodate specific equipment. Therefore, we proposed to remove the radiation treatment vault as a direct PE input from the radiation treatment procedures listed in Table 9, because we believed that the vault is not, itself, medical equipment; and therefore, it is accounted for in the indirect PE methodology.

TABLE 9—HCPCS CODES AFFECTED BY PROPOSED REMOVAL OF RADIATION TREATMENT VAULT

HCPCS	Short descriptor
77373	Sbvt delivery.
77402	Radiation treatment delivery.
77403	Radiation treatment delivery.
77404	Radiation treatment delivery.
77406	Radiation treatment delivery.
77407	Radiation treatment delivery.
77408	Radiation treatment delivery.
77409	Radiation treatment delivery.
77411	Radiation treatment delivery.
77412	Radiation treatment delivery.
77413	Radiation treatment delivery.
77414	Radiation treatment delivery.
77416	Radiation treatment delivery.
77418	Radiation tx delivery imrt.

Comment: We received many comments regarding our proposal to remove the radiation treatment vault as a direct cost from the radiation treatment delivery codes. Although one commenter supported the proposal, most commenters opposed the proposal. In general, commenters reiterated their rationale for inclusion of the vault as a direct practice expense input, asserting that the vault is necessary for the functioning of the equipment, serves a unique medical need, cannot be separated from the treatment delivered

by the linear accelerator, and cannot be repurposed for another use. Commenters also stated that the Internal Revenue Code treats the vault as medical equipment that is separately depreciable from the building itself. For the most part, commenters objected to the removal of the vault given the context of declining Medicare payment for radiation oncology services over the past few years, or in conjunction with the revised radiation treatment code set. Specifically, several commenters suggested that stakeholders cannot provide meaningful comment about the impact of the vault proposal in the context of other pending changes. Some commenters requested a phase-in of any decrease in payment so that providers of radiation therapy services have an opportunity to adjust their practice costs. Several commenters also suggested that the change in payment could exacerbate problems in access to oncology services for Medicare patients.

Response: We appreciate commenters' concerns regarding the proposal to remove the vault as a direct practice expense input. We understand the essential nature of the vault in the provision of radiation therapy services and its uniqueness to a particular piece of medical equipment but are not convinced that either of these factors leads to the conclusion that the vault should be considered medical equipment for purposes of the PE methodology under the PFS. We appreciate the information commenters provided regarding the IRS treatment of the vault under tax laws, but the purposes and goals of the tax code and the PFS PE methodology are different, and, as such, attempts to draw parallels between the two are not necessarily instructive or relevant. We are not finalizing our proposal at this time, but intend to further study the issues raised by the vault and how it relates to our PE methodology.

Comment: A commenter noted that removing the vault as a direct cost also reduces the amount of indirect PE allocated for these procedures, and that this proposal does not shift the vault from direct PE to indirect PE, but rather drops the cost of the vault entirely. Another commenter stated that since the pool of indirect PE RVUs associated with radiation oncology services is fixed, the issue in question is how the indirect costs involved in furnishing treatment services compare to the indirect costs in providing other radiation oncology services.

Response: We understand the concerns of commenters regarding the importance of ensuring that the costs related to the vault are included in the

PE methodology. We want to point out, however, that within the established PE methodology, the allocation of indirect PE to individual codes has significant impact on the PE RVUs that determine Medicare payment for individual services. In other words, we believe it is important for stakeholders to recognize that practice expense costs not included in the direct PE input database contribute to the development of PE RVUs through the data used to allocate indirect PE RVUs. We also want to point out that the pool of indirect PE RVUs is not fixed at the specialty level. Rather, the pool of indirect costs under the entire PFS is maintained from year to year, as delineated in step 11 of the PE methodology above. Therefore, changes in the allocation of indirect PE for particular PFS services based on changes in either direct PE inputs, work RVUs, work time, or utilization data, impacts the amount of indirect PE allocated to all other PFS services, not just those furnished by specialties that furnish that service.

After continued review of the issues pertaining to the vault in the context of the comments, we believe that these issues require further study. Therefore, at this time, we will continue to include the vault as a direct PE input for the services listed in Table 9.

f. Clinical Labor Input Errors

Subsequent to the publication of the CY 2014 PFS final rule with comment period, it came to our attention that, due to a clerical error, the clinical labor type for CPT code 77293 (Respiratory Motion Management Simulation (list separately in addition to code for primary procedure)) was entered as L052A (Audiologist) instead of L152A (Medical Physicist), which has a higher cost per minute. We proposed a correction to the clinical labor type for this service.

Comment: Commenters appreciated our proposal to correct this error.

Response: We appreciate commenters' support for our proposal, and are finalizing the assignment of clinical labor type L152A to code 77293 as proposed. The CY 2015 Direct Practice Expense Input database reflects this correction.

In conducting a routine data review of the database, we also discovered that, due to a clerical error, the RN time allocated to CPT codes 33620 (Apply r&l pulm art bands), 33621 (Transthor cath for stent), and 33622 (Redo compl cardiac anomaly) was entered in the nonfacility setting, rather than in the facility setting where the code is valued. When a service is not valued in a particular setting, any inputs included in that setting are not included in the

calculation of the PE RVUs for that service. Therefore, we proposed to move the RN time allocated to these procedures to the facility setting. The PE RVUs listed in Addendum B reflect these technical corrections.

We did not receive any comments on this proposal; therefore, we are finalizing our proposal to move the RN time allocated to these procedures to the facility setting. The CY 2015 Direct Practice Expense Input database reflects this correction.

g. Work Time

Subsequent to the publication of the CY PFS 2014 final rule with comment period, several inconsistencies in the work time file came to our attention. First, for some services, the total work time, which is used in our PE methodology, did not equal the sum of the component parts (pre-service, intra-service, post-service, and times associated with global period visits). The times in the CY 2015 work time file reflect our corrected values for total work time. Second, for a subset of services, the values in the pre-positioning time, pre-evaluation time, and pre-scrub-dress-wait time, were inadvertently transposed. We note that this error had no impact on calculation of the total times, but has been corrected in the CY 2015 work time file. Third, minor discrepancies for a series of interim final codes were identified between the work time file and the way we addressed these codes in the preamble text. Therefore, we have made adjustments to the work time file to reflect the decisions indicated in the preamble text. The work time file is available on the CMS Web site under the supporting data files for the CY 2015 PFS final rule with comment period at <http://www.cms.gov/PhysicianFeeSched/>. Note that for comparison purposes, the CY 2014 work time file is located at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1600-FC.html>.

Comment: A commenter supported our proposal to correct the work times associated with the procedures affected by this proposal.

Response: We appreciate the commenter's support for our proposal. After consideration of the comment received, we are finalizing our proposal to adjust the work time file as proposed. The work time file is available on the CMS Web site under the supporting data files for the CY 2015 PFS final rule with comment period at <http://www.cms.gov/PhysicianFeeSched/>

h. Updates to Price for Existing Direct Inputs.

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public requests to update equipment and supply price and equipment useful life inputs through annual rulemaking beginning with the CY 2012 PFS proposed rule. During 2013, we received a request to update the price of SD216 (catheter, balloon, esophageal or rectal (graded distention test)) from \$217 to \$237.50. We also received a request to update the price of SL196 (kit, HER-2/neu DNA Probe) from \$105 to \$144.50. We received invoices that documented updated pricing for each of these supply items. We proposed to increase the price associated with these supply items.

We continue to believe it is important to maintain a periodic and transparent process to update the price of items to reflect typical market prices in our ratesetting methodology, and we continue to study the best way to improve our current process. We remind stakeholders that we have difficulty obtaining accurate pricing information. The goal of the current transparent process is to offer the opportunity for the community to both request supply price updates by providing us copies of paid invoices, and to object to proposed changes in price inputs for particular items by providing additional information about prices available to the practitioner community. We remind stakeholders that PFS payment rates are developed within a budget neutral, relative value system, and any increases in price inputs for particular supply items result in corresponding decreases to the relative values of all other direct PE inputs.

We also received a RUC recommendation to update the prices associated with two supply items. Specifically, the RUC recommended that we increase the price of SA042 (pack, cleaning and disinfecting, endoscope) from \$15.52 to \$17.06 to reflect the addition of supply item SJ009 (basin, irrigation) to the pack, and increase the price of SA019 (kit, IV starter) from \$1.37 to \$1.60 to reflect the addition of supply item SA044 (underpad 2 ft. x 3 ft. (Chux)) to the kit. We proposed to update the prices for both of these items based on these recommendations.

Comment: We received several comments regarding our concern about obtaining accurate pricing information for equipment and supply items included in the direct PE database. The RUC indicated that it would continue to work with specialty societies to obtain

paid invoices. A commenter suggested that a sample of paid invoices be obtained from practices and submitted with the PE materials to the RUC, or directly to CMS. Another commenter expressed concern regarding CMS's assertion that invoices are difficult to obtain, given that the RUC process collects lists of resources required to furnish services in the physician office using a standardized process that is typically accompanied by invoices. Another commenter stated that CMS used only the lowest-cost invoice for a particular equipment item since the other invoices included "soft costs," and that CMS should establish an approach that would allow invoices to be used even if they contain "soft costs."

Response: We appreciate the RUC's assistance in obtaining paid invoices from the specialty societies. These invoices are helpful in pricing inputs. We disagree that we use the lowest-cost invoice because it had the lowest cost; rather, we often use the lowest-cost invoice because we do not have a method to use invoices that include costs that are not included as part of the equipment costs, so called "soft costs," within the PE methodology. We do not believe it would serve accuracy or relativity to include as part of the pricing inputs "soft costs" that increase the price of particular supply or equipment items. We would welcome further input on potential approaches for "backing out" these costs.

Comment: One commenter disagreed with CMS's position that the RUC PE Subcommittee's review results in biased or inaccurate resource input costs because the prices are largely maintained in the direct PE input database by CMS.

Response: Although we did not raise this point in the CY 2015 PFS proposed rule, we refer readers to our discussion in previous rulemaking (for example, the CY 2011 PFS final rule with comment period at 75 FR 73250 and the CY 2014 PFS final rule with comment period at 78 FR 74246) regarding issues associated with obtaining appropriate prices for medical equipment and supply items included in the direct PE database. We note that the RUC provides recommendations regarding the use of particular items in furnishing

a service, but does not provide CMS with recommendations regarding the prices of direct PE item. Without assigning a price, the input cannot be factored in to our PE RVU methodology. Our price information is almost exclusively anecdotal, and generally updated only through voluntary submission of a small number of invoices from the same practitioners that furnish and are paid for the services that use the particular inputs. Therefore, we continue to believe there is potential for bias in the information we receive.

Comment: In its comment, the RUC suggested that an annual CMS review of paid invoices for high-cost supplies would be appropriate. A commenter referenced comments made on the CY 2014 PFS final rule with comment period, and expressed agreement with those commenters that the provision of pricing information is sensitive because of issues involving proprietary pricing information and price negotiations for individual practitioners. This commenter also agreed with CMS that such information would be less sensitive if it confirmed inputs contained in the direct PE database. However, the commenter noted that requiring paid invoices from this point forward only partially addresses the concern since many existing inputs are not based on paid invoices; specifically, societies working on inputs for new, revised, or potentially misvalued services are disadvantaged in comparison to many existing inputs due to fee schedule relativity. The commenter suggested that CMS may need to undertake a comprehensive review of all direct PE inputs and obtain paid invoices to systematically address its concerns.

Response: We share commenters' concerns that codes that are being reviewed may be disadvantaged relative to codes that contain input prices that may not be based on paid invoices; and note that we rely on the public process to ensure continued relativity within the direct PE inputs. We encourage interested stakeholders to review updates to prices, as well as prices for new items, to ensure that they appear reasonable and current, and to provide us with updated pricing information, particularly regarding high cost supplies that have a greater impact on relativity.

We refer readers to section II.F. of this final rule with comment period, in which we detail price updates, as well as establish new prices, for inputs included in new, revised, and potentially misvalued codes.

Comment: We received some comments in support of our proposal to update the price for SL196 (kit, HER-2/neu DNA Probe).

Response: We appreciate the commenters' support for our proposal to update the price for SL196. After publication of our proposal, we obtained new information suggesting that further study of the price of this item is necessary before proceeding to update the input price. Therefore, we are not finalizing our proposal to update the price for SL196, and will consider this matter in future rulemaking.

Comment: We did not receive any comments regarding our proposal to update the price for SD216 (catheter, balloon, esophageal or rectal (graded distention test)).

Response: We are finalizing the price updates for SD216.

Comment: We received comments in support of the price update to SA019 (kit, IV starter) and SA042 (pack, cleaning and disinfecting, endoscope).

Response: We appreciate the commenters' support for our proposal to update the price for SA019 and SA042. After consideration of comments received, we are finalizing the price updates for SA019 and SA042.

i. New Standard Supply Package for Contrast Imaging

The RUC recommended creating a new direct PE input standard supply package "Imaging w/contrast, standard package" for contrast enhanced imaging, with a price of \$6.82. This price reflects the combined prices of the medical supplies included in the package; these items are listed in Table 10. We proposed to accept this recommendation, but sought comment on whether all of the items included in the package are used in the typical case. The CY 2015 direct PE database reflects this change and is available on the CMS Web site under the supporting data files for the CY 2015 PFS proposed rule at <http://www.cms.gov/PhysicianFeeSchedule/>.

TABLE 10—STANDARD CONTRAST IMAGING SUPPLY PACKAGE

Medical supply description	SCMS supply code	Unit	Quantity	Price
Kit, IV starter	SA019	Kit	1	\$1.60
Gloves, non-sterile	SB022	Pair	1	0.084

TABLE 10—STANDARD CONTRAST IMAGING SUPPLY PACKAGE—Continued

Medical supply description	SCMS supply code	Unit	Quantity	Price
Angiocatheter 14g–24g	SC001	Item	1	1.505
Heparin lock	SC012	Item	1	0.917
IV tubing (extension)	SC019	Foot	*3	1.590
Needle, 18–27g	SC029	Item	1	0.089
Syringe 20ml	SC053	Item	1	0.558
Sodium chloride 0.9% inj. bacteriostatic (30ml uou)	SH068	Item	1	0.700
Swab-pad, alcohol	SJ053	Item	1	0.013
Total				7.06

*The price for SC019 (IV tubing, (extension)) is \$0.53 per foot.

Comment: Commenters supported our proposal to create the standard supply package for contrast imaging. Some commenters expressed concern that the proposed supply package did not include the full range of supplies typically used when performing contrast imaging. One commenter stated that, for echocardiography labs that utilize contrast-enhanced ultrasound, additional items are typically part of the contrast imaging supply package, including 2x2 gauze pads, a stopcock, and tape. Another commenter suggested that a power injector should also be included in the standard contrast imaging supply package. Commenters also noted that CMS provided limited information regarding how the prices were assigned to the supply items, and pointed to discrepancies between the direct PE database files and the prices quoted in the table.

Response: We appreciate commenters' support for our proposal. We note that the RUC recommendation for the standard contrast imaging supply package also noted that the inputs for CTA and MRA studies would include the standard contrast imaging supply pack in addition to a stop cock (SC050) and additional tubing. While we acknowledge a commenter's suggestion that additional items may be used when echocardiography labs conduct contrast-enhanced ultrasound studies, we do not have information to suggest that these items are used for other imaging studies, such as CT and MRI contrast-enhanced studies. We would welcome more information on whether these items should be included in the newly created standard contrast imaging kit, as well as whether the power injector is used whenever the other inputs in the standard contrast imaging supply package are used, or whether they are used only in certain instances. We note that the reason for the discrepancy in the price for the IV starter kit is that we proposed to update the price at the same time that we proposed to create a new

contrast imaging kit. Since we are finalizing the price update for SA019 (kit, IV starter), we are also finalizing a revised price for the new standard contrast imaging package of \$7.06. Finally, we disagree with the commenter's suggestion that CMS provided limited information about the pricing for the items included in the kit, as these items are existing inputs in the direct PE database, and the codes associated with these items were listed in the table in the proposed rule. After consideration of comments received, we are finalizing our proposal to create a standard contrast imaging supply pack, with a revised price of \$7.06.

j. Direct PE Inputs for Stereotactic Radiosurgery (SRS) Services (CPT Codes 77372 and 77373)

In the CY 2014 PFS final rule with comment period (78 FR 74245), we summarized comments received about whether CPT codes 77372 and 77373 would accurately reflect the resources used in furnishing the typical SRS delivery if there were no coding distinction between robotic and non-robotic delivery methods. Until now, SRS services furnished using robotic methods were billed using contractor-priced G-codes G0339 (Image-guided robotic linear accelerator based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment), and G0340 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment). We indicated that we would consider deleting these codes in future rulemaking.

Most commenters responded that the CPT codes accurately described both services, and the RUC stated that the direct PE inputs for the CPT codes accurately accounted for the resource

costs of the described services. One commenter objected to the deletion of the G-codes but did not include any information to suggest that the CPT codes did not describe the services or that the direct PE inputs for the CPT codes were inaccurate. Based on a review of the comments received, we had no indication that the direct PE inputs included in the CPT codes would not reflect the typical resource inputs involved in furnishing an SRS service. Therefore, in the CY 2014 proposed rule we proposed to recognize only the CPT codes for SRS services, and to delete the G-codes used to report robotic delivery of SRS.

Comment: We received several comments regarding our proposal to delete the SRS G-codes. Some commenters supported our proposal, but most opposed our proposal on the grounds that the direct PE inputs included in the CPT codes do not reflect the typical resource inputs used in furnishing robotic SRS services. Some commenters urged CMS to delay this policy change and continue to contractor price the G-codes until a more appropriate solution can be found.

Response: After consideration of the comments regarding the appropriate inputs to use in pricing the SRS services, we have concluded that at this time, we lack sufficient information to make a determination about the appropriateness of deleting the G-codes and paying for all SRS/SBRT services using the CPT codes. Therefore, we will not delete the G-codes for 2015, but will instead work with stakeholders to identify an alternate approach and reconsider this issue in future rulemaking.

k. Inclusion of Capnograph for Pediatric Polysomnography Services

We proposed to include equipment item EQ358, Sleep capnograph, polysomnography (pediatric), for CPT codes 95782 (Polysomnography; younger than 6 years, sleep staging with

4 or more additional parameters of sleep, attended by a technologist) and 95783 (Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist). Based upon our understanding that capnography is a required element of sleep studies for patients younger than 6 years, we proposed to allocate this equipment item to 95782 for 602 minutes, and 95783 for 647 minutes. Based on the invoice we received for this equipment item, we proposed to price EQ358 at \$4,534.23.

Comment: We received two comments in support of our proposal to include the capnograph in CPT codes 95782 and 95783.

Response: We appreciate commenters' support for our proposal. After consideration of comments received, we are finalizing our proposal to include the capnograph in CPT codes 95782 and 95783.

4. Using OPPS and ASC Rates in Developing PE RVUs

Accurate and reliable pricing information for both individual items and indirect PEs is critical to establish accurate PE RVUs for PFS services. As we have addressed in previous rulemaking, we have serious concerns regarding the accuracy of some of the information we use in developing PE RVUs. In particular, as discussed in the CY 2014 PFS final rule with comment period, we have several longstanding concerns regarding the accuracy of direct PE inputs, including both items and procedure time assumptions, and prices of individual supplies and equipment (78 FR 74248–74250). In addition to the concerns regarding the inputs used in valuing particular procedures, we also noted that the allocation of indirect PE is based on information collected several years ago (as described above) and will likely need to be updated in the coming years.

To mitigate the impact of some of these potentially problematic data used in developing values for individual services, in rulemaking for the CY 2014 PFS, we proposed to limit the nonfacility PE RVUs for individual codes so that the total nonfacility PFS payment amount would not exceed the total combined amount that Medicare would pay for the same code in the facility setting. In developing the proposal, we sought a reliable means for Medicare to set upper payment limits for office-based procedures and believed OPPS and ASC payment rates would provide an appropriate comparison

because these rates are based on relatively more reliable cost information in settings with cost structures that generally would be expected to be higher than in the office setting.

We received many comments regarding our proposal, the vast majority of which urged us to withdraw the proposal. Some commenters questioned the validity of our assumption that facilities' costs for providing all services are necessarily higher than the costs of physician offices or other nonfacility settings. Other commenters expressed serious concerns with the asymmetrical comparisons between PFS payment amounts and OPPS/ASC payment amounts. Finally, many commenters suggested revisions to technical aspects of our proposed policy.

In considering all the comments, however, we were persuaded that the comparison of OPPS (or ASC) payment amounts to PFS payment amounts for particular procedures is not the most appropriate or effective approach to ensuring that PFS payment rates are based on accurate cost assumptions. Commenters noted several flaws with the approach. First, unlike PFS payments, OPPS and ASC payments for individual services are grouped into rates that reflect the costs of a range of services. Second, commenters suggested that since the ASC rates reflect the OPPS relative weights to determine payment rates under the ASC payment system, and are not based on cost information collected from ASCs, the ASC rates should not be used in the proposed policy. For these and other reasons raised by commenters, we did not propose a similar policy for the CY 2015 PFS. If we consider using OPPS or ASC payment rates in developing PFS PE RVUs in future rulemaking, we would consider all of the comments received regarding the technical application of the previous proposal.

After thorough consideration of the comments regarding the CY 2014 proposal, we continue to believe that there are various possibilities for leveraging the use of available hospital cost data in the PE RVU methodology to ensure that the relative costs for PFS services are developed using data that is auditable and comprehensively and regularly updated. Although some commenters questioned the premise that the hospital cost data are more accurate than the information used to establish PE RVUs, we continue to believe that the routinely updated, auditable resource cost information submitted contemporaneously by a wide array of providers across the country is a valid reflection of "relative" resources and could be useful to supplement the

resource cost information developed under our current methodology based upon a typical case that are developed with information from a small number of representative practitioners for a small percentage of codes in any particular year.

Section 220(a)(1) of the PAMA added a new subparagraph (M) under section 1848(c)(2) of the Act that gives us authority to collect information on resources used to furnish services from eligible professionals (including physicians, non-physician practitioners, PTs, OTs, SLPs and qualified audiologists), and other sources. It also authorizes us to pay eligible professionals for submitting solicited information. We will be exploring ways of collecting better and updated resource data from physician practices, including those that are provider-based, and other non-facility entities paid through the PFS. We believe such efforts will be challenging given the wide variety of practices, and that any effort will likely impose some burden on eligible professionals paid through the PFS regardless of the scope and manner of data collection. Currently, through one of the validation contracts discussed in section II.B. of this final rule with comment period, we have been gathering time data directly from physician practices. Through this project, we have learned much about the challenges for both CMS and the eligible professionals of collecting data directly from practices. Our own experience has shown that is difficult to obtain invoices for supply and equipment items that we can use in pricing direct PE inputs.

Many specialty societies also have noted the challenges in obtaining recent invoices for medical supplies and equipment (78 FR 74249). Further, PE calculations rely heavily on information from the Physician Practice Expense Information Survey (PPIS) survey, which, as discussed earlier, was conducted in 2007 and 2008. When we implemented the results of the survey, many in the community expressed serious concerns over the accuracy of this or other PE surveys as a way of gathering data on PE inputs from the diversity of providers paid under the PFS.

In addition to data collection, section 1848(c)(2)(M) of the Act as added by section 220(a) of the PAMA provides authority to develop and use alternative approaches to establish PE relative values, including the use of data from other suppliers and providers of services. We are exploring the best approaches for exercising this authority, including with respect to use of hospital outpatient cost data. We understand that

many stakeholders will have concerns regarding the possibility of using hospital outpatient cost data in developing PE RVUs under the PFS, and we want to be sure we are aware of these prior to considering or developing any future proposal relying on those data.

Therefore, in the CY 2015 PFS proposed rule (79 FR 40333), we sought comment on the possible uses of the Medicare hospital outpatient cost data (not the APC payment amount) in potential revisions of the PFS PE methodology. This could be as a means to validate or, perhaps, in setting the relative resource cost assumptions within the PFS PE methodology. We noted that the resulting PFS payment amounts would not necessarily conform to OPPS payment amounts since OPPS payments are grouped into APCs, while PFS payments would continue to be valued individually and would remain subject to the relativity inherent in establishing PE RVUs, budget neutrality adjustments, and PFS updates. We expressed particular interest in comments that compare such possibilities to other broad-based, auditable, mechanisms for data collection, including any we might consider under the authority provided under section 220(a) of the PAMA. We urged commenters to consider a wide range of options for gathering and using the data, including using the data to validate or set resource assumptions for only a subset of PFS services, or as a base amount to be adjusted by code or specialty-level recommended adjustments, or other potential uses. We appreciate the many thoughtful comments that we received on whether and how to use the OPPS cost data in establishing PE relative values. We will consider these as we continue to think about mechanisms to improve the accuracy of PE values.

In addition to soliciting comments as noted above, in the CY 2015 proposed rule we stated that we continue to seek a better understanding regarding the growing trend toward hospital acquisition of physicians' offices and how the subsequent treatment of those locations as off-campus provider-based outpatient departments affects payments under PFS and beneficiary cost-sharing. MedPAC continues to question the appropriateness of increased Medicare payment and beneficiary cost-sharing when physicians' offices become hospital outpatient departments, and to recommend that Medicare pay selected hospital outpatient services at PFS rates (MedPAC March 2012 and June 2013 *Report to Congress*). We noted that we also remain concerned about the

validity of the resource data as more physician practices become provider-based. Our survey data reflects the PE costs for particular PFS specialties, including a proportion of practices that may have become provider-based since the survey was conducted. Additionally, as the proportion of provider-based offices varies among physician specialties, so do the relative accuracy of the PE survey data. Our current PE methodology primarily distinguishes between the resources involved in furnishing services in two sites of service: The non-facility setting and the facility setting. In principle, when services are furnished in the non-facility setting, the costs associated with furnishing services include all direct and indirect PEs associated with the work and the PE of the service. In contrast, when services are furnished in the facility setting, some costs that would be PEs in the office setting are incurred by the facility. Medicare makes a separate payment to the facility to account for some portion of these costs, and we adjust PEs accordingly under the PFS. As more physician practices become hospital-based, it is difficult to know which PE costs typically are actually incurred by the physician, which are incurred by the hospital, and whether our bifurcated site-of-service differential adequately accounts for the typical resource costs given these relationships. We also have discussed this issue as it relates to accurate valuation of visits within the postoperative period of 10- and 90-day global codes in section II.B.4 of this final rule with comment period.

To understand how this trend is affecting Medicare, including the accuracy of payments made through the PFS, we need to develop data to assess the extent to which this shift toward hospital-based physician practices is occurring. To that end, during CY 2014 rulemaking we sought comment regarding the best method for collecting information that would allow us to analyze the frequency, type, and payment for services furnished in off-campus provider-based hospital departments (78 FR 74427). We received many thoughtful comments. However, the commenters did not present a consensus opinion regarding the options we presented in last year's rule. Based on our analysis of the comments, we stated that we believed the most efficient and equitable means of gathering this important information across two different payment systems would be to create a HCPCS modifier to be reported with every code for physicians' and hospital services

furnished in an off-campus provider-based department of a hospital.

We proposed that the modifier would be reported on both the CMS-1500 claim form for physicians' services and the UB-04 (CMS form 1450) for hospital outpatient claims. (We note that the requirements for a determination that a facility or an organization has provider-based status are specified in § 413.65, and we define a hospital campus to be the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office.)

Therefore, we proposed to collect this information on the type and frequency of services furnished in off-campus provider-based departments in accordance with our authority under section 1848(c)(2)(M) of the Act (as added by section 220(a) of the PAMA) beginning January 1, 2015. The collection of this information would allow us to begin to assess the accuracy of the PE data, including both the service-level direct PE inputs and the specialty-level indirect PE information that we currently use to value PFS services. Furthermore, this information would be critical in order to develop proposed improvements to our PE data or methodology that would appropriately account for the different resource costs among traditional office, facility, and off-campus provider-based settings. We also sought additional comment on whether a code modifier is the best mechanism for collecting this service-level information.

Comment: Many commenters agreed on the need to collect information on the frequency, type, and payment of services furnished in off-campus provider-based departments of hospitals, however, several commenters expressed concern that the HCPCS modifier would create additional administrative burden for providers. Many of these commenters stated that the new modifier would require significant changes to hospitals' billing systems, including a separate charge master for outpatient off-campus PBDs and training for staff on how to use the new modifier. Several commenters thought that education and training would be required for physician offices to attach a modifier to services furnished in an off-campus provider-based department. These same commenters suggested that a new place of service (POS) code would be more appropriate for physician billing. Several commenters suggested that CMS

should re-propose a detailed data collection methodology, test it with providers, make adjustments, and allow additional time for implementation.

Response: While we understand commenters' concerns about the additional administrative burden of reporting a new HCPCS modifier, we have weighed the burden of reporting the modifier for each service against the benefit of having data that will allow us to obtain and assess accurate information on the type and frequency of outpatient hospital services furnished in off-campus provider-based departments, and we do not believe that the modifier is excessively burdensome for providers to report. When billing for hospital services, providers must know where services are furnished in order to accurately complete value code 78 of an outpatient claim or item 32 for service location on the practitioner claim. However, as discussed later in this section, we agree that a POS code on the professional claim allows for the same type of data collection as a modifier and would be less burdensome than the modifier for practitioners. We discuss the timeframe for implementation later in this section.

Comment: Some commenters who were concerned about the administrative burden of the new HCPCS modifier suggested several alternative methods for CMS to collect data on services furnished in off-campus provider-based departments. Several of these commenters recommended that CMS consider establishing of a new POS code for professional claims, or for both professional and hospital claims, because they believed this approach would be less administratively burdensome than attaching a modifier to each service reported on the claim that was furnished in an off-campus provider-based department. Some commenters preferred identifying services furnished in provider-based departments on the Medicare cost report (CMS-2552-10). Some commenters suggested using provider numbers and addresses to identify off-campus PBDs, or changing the provider enrollment process to be able to track this data. Yet other commenters suggested creating a new bill type to track off-campus PBD services.

Commenters generally recommended that CMS choose the least administratively burdensome approach that would ensure accurate data collection, but did not necessarily agree on what approach would optimally achieve that result. Some commenters believed that a HCPCS modifier would more clearly identify specific services furnished at off-campus PBDs, and

would provide better information about the type and level of care furnished. Some commenters believed that a HCPCS modifier would be the least administratively burdensome approach because hospitals and physicians already report a number of claims-based modifiers. However, other commenters stated that additional modifiers would increase administrative burden because this approach would increase the modifiers that would need to be considered when billing.

Response: With respect to creating a new POS code to obtain data on services furnished in off-campus PBDs of a hospital, we note that POS codes are only reported on professional claims and are not included on institutional claims. Therefore, a POS code could not be easily implemented for hospital claims. However, POS codes are already required to be reported on every professional claim, and POS 22 is currently used when physicians' services are furnished in an outpatient hospital department. (More information on existing POS codes is available on the CMS Web site at http://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set.html).

Though we considered proposing a new POS code for professional claims to collect data on services furnished in the off-campus hospital setting, we note that previous GAO and OIG reports (October 2004 A-05-04-0025, January 2005 A-06-04-00046, July 2010 A-01-09-00503, September 2011 A-01-10-00516) have noted frequent inaccuracies in the reporting of POS codes. Additionally, at the time the proposed rule was developed, we had concerns that using a POS code to report this information might not give us the reliable data we are looking to collect, especially if such data were to be cross-walked with hospital claims for the same service, since the hospital claim would have a modifier, not a POS code. However, we have been persuaded by public comments suggesting that use of a POS code on professional claims would be less administratively burdensome than use of a modifier, and would be more familiar to those involved in practitioner billing. Specifically, since a POS code is already required on every professional claim, we believe that creating a new POS code to distinguish outpatient hospital services that are furnished on the hospital campus versus in an off-campus provider-based department would require less staff training and education than would the use of a modifier on the professional claim. Additionally, professional claims only

have space for four modifiers; while a very small percentage of professional claims have four modifiers, required use of an additional modifier for every professional claim could lead to more occurrences where there would not be space for all applicable payment modifiers for a specific service. Unlike institutional claims, we note that a new professional claim is required whenever the place of service changes. That is, even if the same practitioner treats the same patient on the same day in the office and the hospital, the services furnished in the office setting must be submitted on one claim with POS 11 (Office), while those furnished in the outpatient hospital department would be submitted on a separate claim with POS 22 (Outpatient Hospital). Likewise, if a new POS code were to be created for off-campus outpatient provider-based hospital department, a separate claim for services furnished in that setting would be required relative to a claim for outpatient services furnished on the hospital's main campus by the same practitioner to the same patient on the same day. Based on public comments and after further consultation with Medicare billing experts, we believe that use of the POS code on professional claims would be no less accurate than use of a modifier on professional claims in identifying services furnished in off-campus PBDs. In addition, we believe that the POS code would be less administratively burdensome for practitioners billing using the professional claim since a POS code is already required for every professional claim.

With respect to adding new fields to existing claim forms or creating a new bill type, we do not believe that this data collection warrants these measures. We believe that those changes would create greater administrative burden than the proposed HCPCS modifier and POS codes, especially since providers are already accustomed to using modifiers and POS codes. Revisions to the claim form to add new fields or an additional bill type would create significant administrative burden to revise claims processing systems and educate providers that is not necessary given the availability of a modifier and POS codes. Though providers may not be familiar with this new modifier or any new POS code; since these types of codes already exist generally for hospital and professional claims, providers and suppliers should already have an understanding of these types of codes and how to apply them. Finally, we do not believe that expansions to the claim form or use of a new bill type

would provide us with detailed information on exactly which services were furnished in an off-campus PBD versus those furnished on the main campus when those services are furnished on the same day.

We also do not believe that we could accurately determine which services are furnished at off-campus provider-based departments (PBDs) using currently available NPI and facility address data. Hospitals are required to report the nine-digit ZIP code indicating where a service was furnished for purposes of paying properly for physician and anesthesia services paid off the PFS when that ZIP code differs from the master address for the hospital on file in CMS claims systems in value code 78 (pub 100-04, transmittal 1681, February 13, 2009). However, the billing ZIP code for the hospital main campus could be broad enough to incorporate on and off-campus provider-based departments. Further, a ZIP code reported in value code 78 does not allow CMS to distinguish between services furnished in different locations on the same date. Therefore, we do not believe that a comparison of the ZIP code captured in value code 78 and the main campus ZIP code is sufficiently precise.

Finally, while we considered the suggestion that CMS use currently reported Medicare hospital cost report (CMS-2552-10) data to identify services furnished at off-campus PBDs, we note that though aggregate data on services furnished in different settings must be reported through the appropriate cost center, we would not be able to obtain the service-specific level of detail that we would be able to obtain from claims data.

We will take under consideration the suggestion that CMS create a way for hospitals to report their acquisition of physician offices as off-campus PBDs through the enrollment process, although this information, as currently reported, would not allow us to know exactly which services are furnished in off-campus provider based departments and which services are furnished on the hospital's main campus when a hospital provides both on the same day.

Comment: Commenters noted that the proposed modifier would not allow CMS to know the precise location of the off-campus provider-based department for billed services or when services are furnished at different off-campus provider-based locations in the same day.

Response: We agree that neither the proposed modifier nor a POS code provides details on the specific provider-based location for each furnished service. However, we believe

that collecting information on the type and frequency of services furnished at all off-campus locations will assist CMS in better understanding the distribution of services between on and off-campus locations.

Comment: MedPAC believed there may be some value in collecting data on services furnished in off-campus provider-based departments to validate the accuracy of site-of-service reporting when the physician's office is off-campus but bills as an outpatient department. MedPAC indicated that any data collection effort should not prevent the development of policies to align payment rates across settings. MedPAC encouraged CMS to seek legislative authority to set equal payment rates across settings for evaluation and management office visits and other select services.

Response: We thank MedPAC for its support of our data collection efforts to learn more about the frequency and types of services that are being furnished in off-campus PBDs.

Comment: Many commenters suggested that providers would not be able to accurately apply the new modifier by the January 1, 2015 implementation timeline and recommended a one-year delay before providers would be required to apply the modifier to services furnished at off-campus PBDs. Some commenters requested only a six-month delay in implementation. Commenters indicated that significant revisions to internal billing processes would require additional time to implement.

Response: Though we believe that the January 1st effective date that applies to most policies adopted in the final rules with comment period for both the PFS and the OPFS would provide sufficient lead time, we understand commenters' concerns with the proposed timeline for implementation given that the new reporting requirements may require changes to billing systems as well as education and training for staff. With respect to the POS code for professional claims, we will request two new POS codes to replace POS code 22 (Hospital Outpatient) through the POS Workgroup and expect that it will take some time for these new codes to be established. Once the revised POS codes are ready and integrated into CMS claims systems, practitioners would be required to use them, as applicable. More information on the availability of the new POS codes will be forthcoming in subregulatory guidance, but we do not expect the new codes to be available prior to July 1, 2015. There will be no voluntary reporting period of the POS codes for applicable professional claims because

each professional claim requires a POS code in order to be accepted by Medicare. However, we do not view this to be problematic because we intend to give prior notice on the POS coding changes and, as many public commenters noted, because practitioners are already accustomed to using a POS on every claim they submit.

We also are finalizing our proposal to create a HCPCS modifier for hospital services furnished in an off-campus PBD setting; but we are adopting a voluntary reporting period for the new HCPCS modifier for one year. That is, reporting the new HCPCS modifier for services furnished at an off-campus PBD will not be mandatory until January 1, 2016, in order to allow providers time to make systems changes, test these changes, and train staff on use of the new modifier before reporting is required. We welcome early reporting of the modifier and believe a full year of preparation should provide hospitals with sufficient time to modify their systems for accurate reporting.

Comment: Many commenters expressed concern that this data collection would eventually lead to equalizing payment for similar services furnished in the non-facility setting and the off-campus PBD setting. Several commenters noted that the trend of hospitals acquiring physician practices is due to efforts to better integrate care delivery, and suggested that CMS weigh the benefits of care integration when deciding payment changes. Some commenters suggested that CMS should use the data to equalize payment for similar services between these two settings. These commenters suggest that there is little difference in costs and care between the two settings that would warrant the difference in payment. Several of these commenters highlighted beneficiary cost sharing as one reason for site-neutral payment, noting that the total payment amount for hospital outpatient services is generally higher than the total payment amount for those same services when furnished in a physician's office.

Response: We appreciate the comments received. At this time, we are only finalizing a data collection in this final rule with comment period. We did not propose, and therefore, are not finalizing any adjustment to payments furnished in the off-campus PBD setting.

Comment: Several commenters noted that the CMS proposal would not provide additional information on how a physician practice billed prior to becoming an off-campus PBD, which would be important for analyzing the impact of this trend.

Response: We agree that, in analyzing the impact of this trend, it is important to understand physician billing patterns that were in place prior to becoming an off-campus PBD, and we will continue to evaluate ways to analyze claims data to gather this information. We believe that collecting data using the additional modifier and POS code as finalized in this rule will be an important tool in furthering this analysis.

Comment: Some commenters suggested that the term “off-campus” needs to be better defined. Commenters asked how billing would occur for hospitals with multiple campuses since the CMS definition of campus references main buildings and does not include remote locations. One commenter also asked whether the modifier is intended to cover services furnished in free-standing emergency departments.

Response: For purposes of the modifier and the POS codes we are finalizing in this final rule with comment period, we define a “campus” using the definition at § 413.65(a)(2) to be the physical area immediately adjacent to the provider’s main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider’s campus. We agree with commenters that our intent is to capture data on outpatient services furnished off of the hospital’s main campus and off of any of the hospital’s other campuses. The term “remote location of a hospital” is defined in our regulations at section 413.65(a)(2). Under the regulation, a “remote location” includes a hospital campus other than the main hospital campus. Specifically, a remote location is “a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purposes of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider” Therefore, we agree with the commenters that the new HCPCS modifier and the POS code for off-campus PBDs should not be reported for services furnished in remote locations of a hospital. The term “remote location” does not include “satellite” locations of a hospital. However, since a satellite facility is one that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital, the

new HCPCS modifier and the POS code for off-campus hospital PBDs should not be reported for services furnished in satellite facilities. Satellite facilities are described in our regulations at § 412.22(h). Accordingly, reporting of the modifier and the POS code that identifies an off-campus hospital PBD would be required for outpatient services furnished in PBDs that are located beyond 250 yards from the main campus of the hospital, excluding services furnished in a remote location or satellite facility of the hospital.

We also appreciate the comment on emergency departments. We do not intend for hospitals to report the new modifier for services furnished in emergency departments. We note that there is already a POS code for the emergency department, POS 23 (emergency room-hospital), and this would continue to be used on professional claims for services furnished in emergency departments. That is, the new POS code for off-campus hospital PBDs that will be created for purposes of this data collection would not apply to emergency department services. Hospitals and practitioners that have questions about which departments are considered to be “off-campus PBDs” should review additional guidance that CMS releases on this policy and work with the appropriate CMS regional office if individual, specific questions remain.

Comment: Several commenters asked for clarification on when to report the modifier for services furnished both on and off-campus on the same day. Commenters provided several scenarios of visits and diagnostic services furnished on the same day.

Response: The location where the service is actually furnished would dictate the use of the modifier and the POS codes, regardless of where the order for services is initiated. We expect the modifier and the POS code for off-campus PBDs to be reported in locations in which the hospital expends resources to furnish the service in an off-campus PBD setting. For example, hospitals would not report the modifier for a diagnostic test that is ordered by a practitioner who is located in an off-campus PBD when the service is actually furnished on the main campus of the hospital. This issue does not impact use of the POS codes since practitioners submit a different claim for each POS where they furnish services for a specific beneficiary.

Comment: A few commenters asked for clarification on whether their entity constitutes a provider-based department.

Response: Provider-based departments are departments of the hospital that meet the criteria in § 413.65.

Comment: A commenter recommended that CMS publish the data it acquires through adoption of this modifier.

Response: Data collected through the new HCPCS modifier would be part of the Medicare Limited Data Set and would be available to the public for purchase along with the rest of the Limited Data Set. Similarly, professional claims data with revised POS coding would be available as a standard analytic file for purchase.

In summary, after consideration of the comments received, we are finalizing our proposal with modifications. For professional claims, instead of finalizing a HCPCS modifier, in response to comments, we will be deleting current POS code 22 (outpatient hospital department) and establishing two new POS codes—one to identify outpatient services furnished in on-campus, remote or satellite locations of a hospital, and another to identify services furnished in an off-campus hospital PBD setting that is not a remote location of a hospital, a satellite location of a hospital or a hospital emergency department. We will maintain the separate POS code 23 (emergency room-hospital) to identify services furnished in an emergency department of the hospital. These new POS codes will be required to be reported as soon as they become available, however advance notice of the availability of these codes will be shared publicly as soon as practicable.

For hospital claims, we are creating a HCPCS modifier that is to be reported with every code for outpatient hospital services furnished in an off-campus PBD of a hospital. This code will not be required to be reported for remote locations of a hospital defined at § 412.65, satellite facilities of a hospital defined at § 412.22(h) or for services furnished in an emergency department. This 2-digit modifier will be added to the HCPCS annual file as of January 1, 2015, with the label “PO,” the short descriptor “Serv/proc off-campus pbd,” and the long descriptor “Services, procedures and/or surgeries furnished at off-campus provider-based outpatient departments.” Reporting of this new modifier will be voluntary for 1 year (CY 2015), with reporting required beginning on January 1, 2016. Additional instruction and provider education will be forthcoming in subregulatory guidance.

B. Potentially Misvalued Services Under the Physician Fee Schedule

1. Valuing Services Under the PFS

Section 1848(c) of the Act requires the Secretary to determine relative values for physicians' services based on three components: Work, PE, and malpractice. Section 1848(c)(1)(A) of the Act defines the work component to mean, "the portion of the resources used in furnishing the service that reflects physician time and intensity in furnishing the service." In addition, section 1848(c)(2)(C)(i) of the Act specifies that "the Secretary shall determine a number of work relative value units (RVUs) for the service based on the relative resources incorporating physician time and intensity required in furnishing the service."

Section 1848(c)(1)(B) of the Act defines the PE component as "the portion of the resources used in furnishing the service that reflects the general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising practice expenses." Section 1848(c)(2)(C)(ii) of the Act requires that PE RVUs be determined based upon the relative PE resources involved in furnishing the service. (See section II.A. of this final rule with comment period for more detail on the PE component.)

Section 1848(c)(1)(C) of the Act defines the MP component as "the portion of the resources used in furnishing the service that reflects malpractice expenses in furnishing the service." Section 1848(c)(2)(C)(iii) of the Act specifies that MP expense RVUs shall be determined based on the relative MP expense resources involved in furnishing the service. (See section II.C. of this final rule with comment period for more detail on the MP component.)

2. Identifying, Reviewing, and Validating the RVUs of Potentially Misvalued Services

a. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the RVUs established under the PFS. Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) of the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, using the same criteria

used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section I.B. of this final rule with comment period, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC), the Medicare Payment Advisory Commission (MedPAC), and others. For many years, the RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decision-making process as authorized by the law. We may also consider analyses of work time, work RVUs, or direct PE inputs using other data sources, such as Department of Veteran Affairs (VA), National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Physician Quality Reporting Initiative (PQRI) databases. In addition to considering the most recently available data, we also assess the results of physician surveys and specialty recommendations submitted to us by the RUC. We also consider information provided by other stakeholders. We conduct a review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available, in addition to taking into account the results of consultations with organizations representing physicians. In accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs.

In its March 2006 Report to the Congress, MedPAC discussed the importance of appropriately valuing physicians' services, noting that "misvalued services can distort the price signals for physicians' services as well as for other health care services that physicians order, such as hospital services." In that same report MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, "When a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish

that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it." We believe services can also become overvalued when PE declines. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases or PE rises.

As MedPAC noted in its March 2009 Report to Congress, in the intervening years since MedPAC made its initial recommendations, "CMS and the RUC have taken several steps to improve the review process." Also, since that time the Congress added section 1848(c)(2)(K)(ii) to the Act, which augments our efforts. It directs the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following seven categories:

- Codes and families of codes for which there has been the fastest growth;
- Codes and families of codes that have experienced substantial changes in PEs;
- Codes that are recently established for new technologies or services;
- Multiple codes that are frequently billed in conjunction with furnishing a single service;
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment;
- Codes which have not been subject to review since the implementation of the RBRVS (the so-called 'Harvard-valued codes'); and
- Other codes determined to be appropriate by the Secretary.

Section 220(c) of the Protecting Access to Medicare Act of 2014 (PAMA) further expanded the categories of codes that the Secretary is directed to examine by adding nine additional categories. These are:

- Codes that account for the majority of spending under the PFS;
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time;
- Codes for which there may be a change in the typical site of service since the code was last valued;
- Codes for which there is a significant difference in payment for the same service between different sites of service;
- Codes for which there may be anomalies in relative values within a family of codes;

- Codes for services where there may be efficiencies when a service is furnished at the same time as other services;

- Codes with high intra-service work per unit of time;

- Codes with high PE RVUs; and
- Codes with high cost supplies.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section of the Act also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) that may include consolidation of individual services into bundled codes for payment under the physician fee schedule.

b. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous potentially misvalued codes as specified in section 1848(c)(2)(K)(ii) of the Act, and we plan to continue our work examining potentially misvalued codes as authorized by statute over the coming years. As part of our current process, we identify potentially misvalued codes for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The RUC, through its own processes, also identifies potentially misvalued codes for review. Through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule with comment period, other individuals and stakeholder groups submit nominations for review of potentially misvalued codes as well.

Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have

reviewed over 1,250 potentially misvalued codes to refine work RVUs and direct PE inputs. We have assigned appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the CY 2012 PFS final rule with comment period (76 FR 73052 through 73055). In the CY 2012 final rule with comment period, we finalized our policy to consolidate the review of physician work and PE at the same time (76 FR 73055 through 73958), and established a process for the annual public nomination of potentially misvalued services.

In the CY 2013 final rule with comment period, we built upon the work we began in CY 2009 to review potentially misvalued codes that have not been reviewed since the implementation of the PFS (so-called “Harvard-valued codes”). In CY 2009, we requested recommendations from the RUC to aid in our review of Harvard-valued codes that had not yet been reviewed, focusing first on high-volume, low intensity codes (73 FR 38589). In the fourth Five-Year Review, we requested recommendations from the RUC to aid in our review of Harvard-valued codes with annual utilization of greater than 30,000 (76 FR 32410). In the CY 2013 final rule with comment period, we identified Harvard-valued services with annual allowed charges that total at least \$10,000,000 as potentially misvalued. In addition to the Harvard-valued codes, in the CY 2013 final rule with comment period we finalized for review a list of potentially misvalued codes that have stand-alone PE (codes with physician work and no listed work time, and codes with no physician work that have listed work time).

In the CY 2014 final rule with comment period, we finalized for review a list of potentially misvalued services. We included on the list for review ultrasound guidance codes that had longer procedure times than the typical procedure with which the code is billed to Medicare. We also finalized our proposal to replace missing post-operative hospital E/M visit information and work time for approximately 100 global surgery codes. For CY 2014, we also considered a proposal to limit PFS payments for services furnished in a nonfacility setting when the nonfacility PFS payment for a given service exceeds the combined Medicare Part B payment for the same service when it is furnished in a facility (separate payments being made to the practitioner under the PFS and to the facility under the OPFS).

Based upon extensive public comment, we did not finalize this proposal. We address our current consideration of the potential use of OPFS data in establishing RVUs for PFS services, as well as comments received, in section II.B. of this final rule with comment period.

c. Validating RVUs of Potentially Misvalued Codes

Section 1848(c)(2)(L) of the Act requires the Secretary to establish a formal process to validate RVUs under the PFS. The Act specifies that the validation process may include validation of work elements (such as time, mental effort and professional judgment, technical skill and physical effort, and stress due to risk) involved with furnishing a service and may include validation of the pre-, post-, and intra-service components of work. The Secretary is directed, as part of the validation, to validate a sampling of the work RVUs of codes identified through any of the 16 categories of potentially misvalued codes specified in section 1848(c)(2)(K)(ii) of the Act. Furthermore, the Secretary may conduct the validation using methods similar to those used to review potentially misvalued codes, including conducting surveys, other data collection activities, studies, or other analyses as the Secretary determines appropriate to facilitate the validation of RVUs of services.

In the CY 2011 PFS proposed rule (75 FR 40068) and CY 2012 PFS proposed rule (76 FR 42790), we solicited public comments on possible approaches, methodologies, and data sources that we should consider for a validation process. We provided a summary of the comments along with our responses in the CY 2011 PFS final rule with comment period (75 FR 73217) and the CY 2012 PFS final rule with comment period (76 FR 73054 through 73055).

We contracted with two outside entities to develop validation models for RVUs. Given the central role of time in establishing work RVUs and the concerns that have been raised about the current time values used in rate setting, we contracted with the Urban Institute to collect time data from several practices for services selected by the contractor in consultation with CMS. These data will be used to develop time estimates. The Urban Institute will use a variety of approaches to develop objective time estimates, depending on the type of service. Objective time estimates will be compared to the current time values used in the fee schedule. The project team will then convene groups of physicians from a

range of specialties to review the new time data and their potential implications for work and the ratio of work to time. The Urban Institute has prepared an interim report, *Development of a Model for the Valuation of Work Relative Value Units*, which discusses the challenges encountered in collecting objective time data and offers some thoughts on how these can be overcome. This interim report is available on the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/RVUs-Validation-UrbanInterimReport.pdf>. Collection of time data under this project has just begun. A final report will be available once the project is complete.

The second contract is with the RAND Corporation, which is using available data to build a validation model to predict work RVUs and the individual components of work RVUs, time, and intensity. The model design was informed by the statistical methodologies and approach used to develop the initial work RVUs and to identify potentially misvalued procedures under current CMS and RUC processes. RAND will use a representative set of CMS-provided codes to test the model. RAND consulted with a technical expert panel on model design issues and the test results. We anticipate a report from this project by the end of the year and will make the report available on the CMS Web site.

Descriptions of both projects are available on the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/RVUs-Validation-Model.pdf>.

We acknowledge comments received regarding the Urban Institute and RAND projects, but note that we did not solicit comments on these projects because we made no proposals related to them. Any changes to payment policies under the PFS that we might make after considering these reports would be issued in a proposed rule and subjected to public comment before they would be finalized and implemented.

3. CY 2015 Identification and Review of Potentially Misvalued Services

a. Public Nomination of Potentially Misvalued Codes

In the CY 2012 PFS final rule with comment period, we finalized a process for the public to nominate potentially misvalued codes (76 FR 73058). The public and stakeholders may nominate potentially misvalued codes for review

by submitting the code with supporting documentation during the 60-day public comment period following the release of the annual PFS final rule with comment period. Supporting documentation for codes nominated for the annual review of potentially misvalued codes may include the following:

- Documentation in the peer reviewed medical literature or other reliable data that there have been changes in physician work due to one or more of the following: Technique; knowledge and technology; patient population; site-of-service; length of hospital stay; and work time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work, that is, diffusion of technology.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of work time, work RVU, or direct PE inputs using other data sources (for example, VA NSQIP, STS National Database, and the PQRS databases).
- National surveys of work time and intensity from professional and management societies and organizations, such as hospital associations.

After we receive the nominated codes during the 60-day comment period following the release of the annual PFS final rule with comment period, we evaluate the supporting documentation and assess whether the nominated codes appear to be potentially misvalued codes appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate whether we are proposing each nominated code as a potentially misvalued code.

During the comment period to the CY 2014 final rule with comment period, we received nominations and supporting documentation for four codes to be considered as potentially misvalued codes. Although we evaluated the supporting documentation for two of the nominated codes to ascertain whether the submitted

information demonstrated that the code should be proposed as potentially misvalued, we did not identify the other two codes until after the publication of the proposed rule. We apologize for this oversight and will address the nomination of CPT codes 92227 and 92228 in the proposed rule for CY 2016.

We proposed CPT code 41530 (submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session) as potentially misvalued based on public nomination due to a significant decrease in two of the direct PE inputs.

Comment: The commenter that nominated this code as potentially misvalued thanked CMS for proposing this code as potentially misvalued, but indicated that the RUC had made recommendations for this code for CY 2015 and further review was no longer necessary. Another commenter suggested that this code should be removed from the list of potentially misvalued codes since it saves Medicare millions of dollars per year.

Response: The RUC only provided us with recommendations for PE inputs for CPT code 41530. Under our usual process, we value work and PE at the same time and would expect to receive RUC recommendations on both before we revalue this service. We disagree with the commenter's statement that codes that may save money for the Medicare program should not be considered as potentially misvalued. Our aim, consistent with our statutory directive, is to value all services appropriately under the PFS to reflect the relative resources involved in furnishing them. After consideration of public comments, we are finalizing CPT code 41530 as potentially misvalued.

We did not propose CPT code 99174 (instrument-based ocular screening (for example, photoscreening, automated-refraction), bilateral) as potentially misvalued, because it is a non-covered service, and we only consider nominations of active codes that are covered by Medicare at the time of the nomination (see 76 FR 73059).

Comment: Commenters did not disagree with CMS not proposing this code as potentially misvalued, but did raise a variety of comments about the code that were unrelated to our proposal.

Response: We continue to believe that our policy to limit the designation of potentially misvalued to those codes that are covered by Medicare is appropriate, so that we focus our limited resources on those services that have an impact on the Medicare program and its beneficiaries. Therefore, we are not including CPT code 99174 on

our final list of potentially misvalued codes for CY 2015.

b. Potentially Misvalued Codes

(1) Review of High Expenditure Services Across Specialties With Medicare Allowed Charges of \$10,000,000 or More

We proposed 68 codes listed in Table 11 as potentially misvalued codes under the newly established statutory category, “codes that account for the majority of spending under the physician fee schedule.” To develop this list, we identified the top 20 codes by specialty (using the specialties used in Table 11) in terms of allowed charges. We excluded those codes that we have reviewed since CY 2009, those codes with fewer than \$10 million in allowed charges, and E/M services. E/M services were excluded for the same reason that we excluded them in a similar review for CY 2012. The reason was explained in the CY 2012 final rule with comment period (76 FR 73062 through 73065).

We stated that we believed that a review of the codes in Table 11 is warranted to assess changes in physician work and to update direct PE inputs since these codes have not been reviewed since CY 2009 or earlier. Furthermore, since these codes have significant impact on PFS payment at the specialty level, a review of the relativity of the codes is essential to ensure that the work and PE RVUs are appropriately relative within the specialty and across specialties, as discussed previously. For these reasons, we proposed the codes listed in Table 11 as potentially misvalued.

TABLE 11—POTENTIALLY MISVALUED CODES IDENTIFIED THROUGH THE HIGH EXPENDITURE BY SPECIALTY SCREEN

HCPSCS	Short descriptor
11100 ..	Biopsy skin lesion.
11101 ..	Biopsy skin add-on.
11730 ..	Removal of nail plate.
11750 ..	Removal of nail bed.
14060 ..	Tis trnfr e/n/e/l 10 sq cm/.
17110 ..	Destruct b9 lesion 1–14.
31575 ..	Diagnostic laryngoscopy.
31579 ..	Diagnostic laryngoscopy.
36215 ..	Place catheter in artery.
36475 ..	Endovenous rf 1st vein.
36478 ..	Endovenous laser 1st vein.
36870 ..	Percut thrombect av fistula.
51720 ..	Treatment of bladder lesion.
51728 ..	Cystometrogram w/wp.
51798 ..	Us urine capacity measure.
52000 ..	Cystoscopy.
55700 ..	Biopsy of prostate.
65855 ..	Laser surgery of eye.
66821 ..	After cataract laser surgery.
67228 ..	Treatment of retinal lesion.

TABLE 11—POTENTIALLY MISVALUED CODES IDENTIFIED THROUGH THE HIGH EXPENDITURE BY SPECIALTY SCREEN—Continued

HCPSCS	Short descriptor
68761 ..	Close tear duct opening.
71010 ..	Chest x-ray 1 view frontal.
71020 ..	Chest x-ray 2vw frontal&latl.
71260 ..	Ct thorax w/dye.
73560 ..	X-ray exam of knee 1 or 2.
73562 ..	X-ray exam of knee 3.
73564 ..	X-ray exam knee 4 or more.
74183 ..	Mri abdomen w/o & w/dye.
75978 ..	Repair venous blockage.
76536 ..	Us exam of head and neck.
76700 ..	Us exam abdom complete.
76770 ..	Us exam abdo back wall comp.
76775 ..	Us exam abdo back wall lim.
77263 ..	Radiation therapy planning.
77334 ..	Radiation treatment aid(s).
78452 ..	Ht muscle image spect mult.
88185 ..	Flowcytometry/tc add-on.
91110 ..	Gi tract capsule endoscopy.
92136 ..	Ophthalmic biometry.
92250 ..	Eye exam with photos.
92557 ..	Comprehensive hearing test.
93280 ..	Pm device progr eval dual.
93306 ..	Tte w/doppler complete.
93351 ..	Stress tte complete.
93978 ..	Vascular study.
94010 ..	Breathing capacity test.
95004 ..	Percut allergy skin tests.
95165 ..	Antigen therapy services.
95957 ..	Eeg digital analysis.
96101 ..	Psycho testing by psych/phys.
96118 ..	Neuropsych tst by psych/phys.
96372 ..	Ther/proph/diag inj sc/im.
96375 ..	Tx/pro/dx inj new drug add-on.
96401 ..	Chemo anti-neopl sq/im.
96409 ..	Chemo iv push sngl drug.
97032 ..	Electrical stimulation.
97035 ..	Ultrasound therapy.
97110 ..	Therapeutic exercises.
97112 ..	Neuromuscular reeducation.
97113 ..	Aquatic therapy/exercises.
97116 ..	Gait training therapy.
97140 ..	Manual therapy 1/> regions.
97530 ..	Therapeutic activities.
G0283	Elec stim other than wound.

Comment: Many commenters disagreed with the high expenditure screen in principle, stating that the frequency with which a service is furnished (and therefore the total expenditures) is not an indication that the service is misvalued. Specifically, commenters explained that many of the services are highly utilized because of the nature of the Medicare beneficiary population, and not because there is abuse or overutilization. Commenters asserted that the current misvalued code screens can produce a redundant list of potentially misvalued codes while failing to identify codes that are being incorrectly reported. Another commenter urged CMS to work with the RUC to ensure that the code lists identified by the misvalued code screens are accurate. A commenter

asked CMS to provide justification for including codes with charges greater than \$10 million on the potentially misvalued codes list. Some commenters urged us to reconsider including particular families of codes that were reviewed prior to 2009; others asked that CMS exclude all codes that have been reviewed in the last 10 years; and still others requested that we exclude codes that were bundled several years ago. A commenter stated that the emphasis on codes with spending of more than \$10 million demonstrates an agenda to cut spending rather than to ensure appropriate payment, and expressed concern that CMS was simply nominating high value services. Commenters recommended that CMS not finalize its proposed list of potentially misvalued codes, and instead develop a more targeted list of codes that are likely to be misvalued (not just potentially misvalued). Commenters wanted CMS to exempt codes when there have not been fundamental changes in the way the services are furnished or there is no indication that their values are inaccurate, so that specialty societies do not have to go through the work of reviewing them.

Several commenters questioned the statutory authority for CMS's proposal. One commenter questioned CMS's authority under the relevant statute to select potentially misvalued codes by specialty. The commenter stated that identifying the top 20 codes by specialty in terms of allowed charges does not appear to align with a direct reading of the relevant statutory authority, which allows CMS to identify codes that account for the majority of spending under the PFS, but does not provide for the identification of codes by specialty. The commenter said that a more direct interpretation of the statutory authority would be to select codes based on allowed charges irrespective of specialty, and then to narrow the universe of codes based upon the top codes in terms of allowed charges. Another commenter believed the proposed screen did not comport with the statutory selection criteria because the majority or near majority of spending under the PFS is for evaluation and management (E/M) codes, which CMS excluded from review. The commenter said that if CMS believes that E/M services should not be reviewed—a position the commenter said they would certainly understand—then such a determination is sufficient to meet the statutory mandate to review codes accounting for the majority of PFS spending, and it would then be

appropriate for CMS and the RUC to focus efforts on other categories of potentially misvalued codes. The commenter urged CMS at the very least to develop a more targeted list of potentially misvalued services in the category of codes accounting for the majority of PFS spending, and to include codes that are likely to be misvalued, not just potentially misvalued.

Response: Potentially misvalued code screens are intended to identify codes that are possibly misvalued. By definition, these screens do not assert that codes are certainly or even likely misvalued. As we discussed in the CY 2012 PFS final rule with comment period (76 FR 73056), the screens serve to focus our limited resources on categories of codes where there is a high risk of significant payment distortions. One goal is to avoid perpetuating payment for the services at a rate that does not appropriately reflect the relative resources involved in furnishing the service. In implementing this statutory provision, we consider whether the codes meeting the screening criteria have a significant impact on payment for all PFS services due to the budget neutral nature of the PFS. That is, if codes meeting the screening criteria are indeed misvalued, they would be inappropriately impacting the relative values of all PFS services. Addressing included codes therefore indirectly addresses other codes that do not meet the screening criteria but are themselves misvalued because high expenditure codes are misvalued. We agree with the commenters that high program expenditures and high utilization have varying causes and do not necessarily reflect misvalued codes. However, we continue to believe that the high expenditure screen is nevertheless an appropriate means of focusing our reviews, ensuring appropriate relativity among PFS services, and identifying services that are either over or undervalued. The high expenditure screen is likely to identify misvalued codes, both directly and indirectly.

Regarding screening for codes by specialty, as we discussed above, the included codes have significant impact on PFS payment at the specialty level, therefore a review of the relativity of the codes is essential to ensure that the work and PE RVUs are appropriately relative within the specialty and across specialties. We mentioned in the CY 2012 final rule with comment period how stakeholders have noted that many of the services previously identified under the potentially misvalued codes initiative were concentrated in certain

specialties. To develop a robust and representative list of codes for review, we examine the highest PFS expenditure services by specialty and we identify those codes that have not been recently reviewed (76 FR 73060).

Although we understand commenters' concerns that the screens can produce redundant results, we note that we exempted codes that have been reviewed since 2009 for this very reason. We believe that the practice of medicine can change significantly over a 10-year period, and disagree with commenters' suggestions that no changes would occur over a 10-year period that would significantly affect a procedure's valuation.

Regarding the exclusion of E/M services, we refer the commenters to the extensive discussion in the CY 2012 PFS final rule with comment period (76 FR 73060 through 73065). It is true that E/M services account for significant volume under the PFS, but there are significant issues with reviewing these codes as discussed in the CY 2012 final rule with comment period, and as a result we did not propose to include these codes as potentially misvalued.

Comment: Some commenters suggested other screens that could be used to identify misvalued codes. In addition, even though our proposal only relates to identifying potentially misvalued codes, some commenters commented on our mechanisms for re-valuing misvalued codes.

Response: The only screen for which we made a proposal and sought comments was the high expenditure screen. However, we will consider the suggestions for other screens as we develop proposals in future years. Similarly, our proposal only related to identifying potentially misvalued codes and not how to re-value them if they were finalized as potentially misvalued.

Comment: Several commenters requested that CMS postpone the review of potentially misvalued codes until the revised process we proposed for reviewing new, revised, and potentially misvalued codes is in place.

Response: Although we believe that the revised process for reviewing new, revised, and potentially misvalued codes will improve the transparency of the PFS code review process, we do not believe it is appropriate to postpone the review of all potentially misvalued codes until the new process is implemented. We note that the codes identified in this rule as potentially misvalued would be revalued under the new process, which will be phased in starting for CY 2016 and will apply for all codes revalued for CY 2017.

Comment: Commenters raised several codes that they believed should not be included in the high expenditure screen for a variety of reasons, for example if the code is related to other codes that were recently reviewed and the utilization for the identified service is expected to change significantly as a result of coding changes in the family. Commenters also suggested that codes that have been referred to the CPT Editorial Panel should be excluded from the potentially misvalued codes list.

Response: We acknowledge commenters' suggestion that we exclude particular codes from the screen, but since we are not finalizing a particular list of codes for this screen in this final rule we are not addressing these at this time. We note that we do not agree with commenters that codes that have been referred to CPT by the RUC should be excluded from the potentially misvalued list; rather, we believe that only when these codes are either deleted or revised, and/or we receive new RUC recommendations for re-valuing these codes, would it be appropriate to remove these services from the list.

Comment: A commenter suggested that CMS's high expenditure screen may not account for the fact that many radiology codes have already gone through numerous five-year reviews; have well-established RVUs that are included on the RUC's multispecialty point of comparison (MPC) list; have been included in new, bundled codes; or have PE RVUs that were affected by changes in clinical labor times or equipment utilization assumption changes. The commenter also suggested that the screens do not account for the value that patients receive in terms of better, timelier diagnoses and avoidance of invasive procedures.

Response: We acknowledge that certain types of procedures have been identified through multiple screens; however, we continue to believe that it is appropriate to include most codes that are identified via these screens and not to exclude codes simply because many other procedures furnished by that specialty have already been reviewed. We further note that the presence of codes on the MPC list makes the case for their review more compelling, given their importance in ensuring overall relativity throughout the PFS. With respect to changes in PE RVUs, we note that cross-cutting policies that affect large numbers of codes are aimed at ensuring overall relativity but do not address the inputs associated with each procedure affected by the change. Finally, a code's status as potentially misvalued does not imply

that the service itself is not of inherent value; rather, that its valuation may be inaccurate in either direction.

After considering the comments received, as well as the other proposals we are finalizing, we believe it is appropriate to finalize the high expenditure screen as a tool to identify potentially misvalued codes. However, given the resources required over the next several years to revalue the services with global periods, we believe it is best to concentrate our efforts on these valuations. Therefore, we are not finalizing the codes identified through the high expenditure screen as potentially misvalued at this time. Also, we are not responding to comments at this time regarding whether particular codes should or should not be included in the high expenditure code screen and identified as potentially misvalued codes. We will re-run the high expenditure screen at a future date, and will propose at that time the specific set of codes to be reviewed that meet the high expenditure criteria.

(2) Epidural Injection and Fluoroscopic Guidance—CPT Codes 62310, 62311, 62318, 62319, 77001, 77002 and 77003

For CY 2014, we established interim final rates for four epidural injection procedures, CPT codes 62310 (Injection(s), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; cervical or thoracic), 62311 (Injection(s), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; lumbar or sacral (caudal)), 62318 (Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, includes contrast for localization when performed, epidural or subarachnoid; cervical or thoracic) and 62319 (Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, includes contrast for localization when performed,

epidural or subarachnoid; lumbar or sacral (caudal)). These interim final values resulted in CY 2014 payment reductions from the CY 2013 rates for all four procedures.

In the CY 2014 final rule with comment period (78 FR 74340), we described in detail our interim valuation of these codes. We indicated we established interim final work RVUs for these codes that were less than those recommended by the RUC because we did not believe that the RUC-recommended work RVUs accounted for the substantial decrease in time it takes to furnish these services as reflected in the RUC survey data for these four codes. Since the RUC provided no indication that the intensity of the procedures had changed, we indicated that we believed the work RVUs should reflect the reduction in time. We also established interim final direct PE inputs for these four codes based on the RUC-recommended inputs without any refinement. These recommendations included the removal of the radiographic-fluoroscopy room for CPT codes 62310, 62311, and 62318 and a portable C-arm for CPT code 62319.

In response to the comments we received objecting to the CY 2014 interim final values for these codes, we looked at other injection procedures. Other injection procedures, including some that commenters recommended we use to value these epidural injection codes, include the work and practice expenses of image guidance in the injection code. In the proposed rule, we detailed many of these procedures, which include the image guidance in the injection CPT code. Since our analysis of the Medicare data and comments received on the CY 2014 final rule with comment period indicated that these services are typically furnished with imaging guidance, we believe it would be appropriate for the codes to be bundled and the inputs for image guidance to be included in the valuation of the epidural injection codes as it is for transforaminal and paravertebral codes. We stated that we did not believe the epidural injection codes can be appropriately valued without considering the image guidance, and that bundling image guidance will help assure relativity with other injection codes that include the image guidance. To determine how to appropriately value resources for the combined codes, we indicated that we believed more information is needed. Accordingly, we proposed to include CPT codes 62310, 62311, 62318, and 62319 on the potentially misvalued code list so that we can obtain information to value them with the

image guidance included. In the meantime, we proposed to use the CY 2013 input values for CPT codes 62310, 62311, 62318 and 62319 to value these codes for CY 2015. Specifically, we proposed to use the CY 2013 work RVUs and work times.

Because it was clear that inputs that are specifically related to image guidance, such as the radiographic fluoroscopic room, are included in these proposed direct PE inputs for the epidural injection codes, we believed allowing separate reporting of the image guidance codes would overestimate the resources used in furnishing the overall service. To avoid this situation, we also proposed to prohibit the billing of image guidance codes in conjunction with these four epidural injection codes. We stated that we believed our two-tiered proposal to utilize CY 2013 input values for this family while prohibiting separate billing of imaging guidance best ensures that appropriate reimbursements continue to be made for these services, while we gather additional data and input on the best way to value them through codes that include both the injection and the image guidance.

Comment: The commenters did not object to identifying these codes as potentially misvalued and generally agreed with our proposal to revert to the 2013 inputs for CY 2015.

Response: We appreciate support for our proposal.

Comment: Several commenters agreed that it would be appropriate to bundle the image guidance with the epidural procedures. Other commenters suggested that we create both a bundled code and a stand-alone epidural injection code.

Response: We appreciate commenters' support for our proposal to bundle image guidance with the epidural procedures. As part of the review process, consideration can be given to how to best implement bundled codes.

Comment: Other commenters expressed concern that the bundling approach CMS proposed to use until these codes are reviewed did not incorporate the work or time for fluoroscopy. Some requested that we add the payment for fluoroscopic guidance to the epidural injection codes, as we have done in the past for facet joint injections and other services. Commenters requested that we continue to allow the image guidance codes to be separately billed until these services are revalued. Another commenter suggested that it may be premature to prohibit separate billing for image guidance, as there is considerable variation on the

use of fluoroscopic guidance between codes within this family.

Response: We understand commenters' concerns about our proposal to prohibit separate billing for image guidance, and note that these concerns are part of the reason we are referring these codes to the RUC as potentially misvalued. However, given that significant resources are allocated to fluoroscopic guidance within the current injection codes, we do not believe it is appropriate to continue to allow the image guidance to be separately billed while we evaluate these epidural injection codes as potentially misvalued services.

After considering comments received, we are finalizing CPT codes 62310, 62311, 62318, and 62319 as potentially misvalued, finalizing the proposed RVUs for these services, and prohibiting separate billing of image guidance in conjunction with these services.

(3) Neurostimulator Implantation (CPT Codes 64553 and 64555)

We proposed CPT codes 64553 (Percutaneous implantation of neurostimulator electrode array; cranial nerve) and 64555 (Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)) as potentially misvalued after stakeholders questioned whether the codes included the appropriate direct PE inputs when furnished in the nonfacility setting.

Comment: A commenter encouraged CMS to include these codes on the potentially misvalued code list to ensure that they are adequately reimbursed in the nonfacility setting, while another commenter disagreed that the work for CPT codes 64553 and 64555 needed to be reviewed.

Response: In general, when a code is proposed as potentially misvalued, unless we receive information that clearly demonstrates it is not potentially misvalued, we finalize the code as potentially misvalued. When we finalize a code as potentially misvalued, we then review the inputs for the code. As a result of such review, inputs can be adjusted either upward or downward.

We appreciate the support for our proposal expressed by some commenters. Since the commenter opposing the addition of these codes to the potentially misvalued code list did not provide justification for its assertion that the work RVUs for CPT codes 64553 and 64555 did not need to be reviewed, after consideration of comments received, we are finalizing CPT codes 64553 and 64555 as potentially misvalued.

(4) Mammography (CPT Codes 77055, 77056, and 77057, and HCPCS Codes G0202, G0204, and G0206)

Medicare currently pays for mammography services through both CPT codes, (77055 (mammography; unilateral), 77056 (mammography; bilateral) and 77057 (screening mammography, bilateral (2-view film study of each breast))) and HCPCS G-codes, (G0202 (screening mammography, producing direct digital image, bilateral, all views), G0204 (diagnostic mammography, producing direct digital image, bilateral, all views), and G0206 (diagnostic mammography, producing direct digital image, unilateral, all views)). The CPT codes were designed to be used for mammography regardless of whether film or digital technology is used. However, for Medicare purposes, the HCPCS G-codes were created to describe mammograms using digital technology in response to special payment rules for digital mammography included in the Medicare Benefit Improvements and Protection Act of 2000 (BIPA).

The RUC recommended that CMS update the direct PE inputs for all imaging codes to reflect the migration from film-to-digital storage technologies since digital storage is now typically used in imaging services. Review of the Medicare data with regard to the application of this policy to mammography confirmed that virtually all mammography is now digital. As a result, we proposed that CPT codes 77055, 77056, and 77057 be used to report mammography regardless of whether film or digital technology is used, and to delete the HCPCS G-codes G0202, G0204, and G0206. We proposed to establish values for the CPT codes by crosswalking the values established for the digital mammography G-codes for CY 2015. (See section II.B. of this final rule with comment period for more discussion of this policy.) In addition, since the G-code values have not been evaluated since they were created in CY 2002 we proposed to include CPT codes 77055, 77056, and 77057 on the list of potentially misvalued codes.

Comment: With regard to whether the mammography codes should be included on the potentially misvalued codes list, commenters had differing opinions. One commenter stated that the work RVUs for digital mammography are the same as those for analog mammography, and maintained that the BIPA-directed payment for digital mammography of 1.5 times the TC of the analog mammography codes appropriately captures the practice expense resources required for digital

mammography. Another commenter stated that digital mammography rates resulted from a statutory construct and do not reflect the actual costs of the digital resources necessary to furnish the services. One commenter noted that moving from the non-resource-based values to resource-based values will result in a significant reduction to the valuation of these services, and that this reduction will result from the resource-based PE methodology, not from the RUC review. Another commenter indicated that the RUC should not survey these codes, but requested that if the RUC does survey these codes, they should not do so until after CMS finalizes the new breast tomosynthesis codes (3D mammography) and film-to-digital transition. Another commenter indicated that CMS needed to consider that three-dimensional (3D) mammography codes involve additional resources over the two-dimensional (2D) mammography codes. A commenter suggested that this proposal fails to take into account the increasing use of tomography.

Response: The commenters' disagreement about whether these codes are misvalued would suggest that a review is warranted. Given that more than a decade has passed since these services were reviewed, we continue to believe that it is appropriate to review the work RVUs for these services. By including these codes on the potentially misvalued code list, we will have information to determine whether the current values are still appropriate. Finally, we anticipate that the survey results for the mammography codes will reflect the equipment that is typically used. We note that until these services are reviewed, we do not have adequate information to respond to the suggestion that the valuation for these services will be significantly reduced. However, we do acknowledge that the PE methodology is not intended to account for the actual costs in furnishing a service; rather, it is required to account for the relative resources in furnishing that service. We also note that there are new CPT codes for reporting mammography using tomosynthesis and we have RUC recommendations for these codes. We believe it is most appropriate to value the mammography code family together, and receipt of RUC recommendations on the other mammography codes will assist us in our review. Accordingly, we are including all mammography codes except those newly created for tomosynthesis on the potentially misvalued code list.

Comment: Although commenters agreed with our assessment that digital

technology has replaced analog mammography as typical, not all agreed that it was appropriate to delete G-codes and use the CPT codes. One commenter supported the deletion of the G-codes. Other commenters suggested that deletion of the G-codes was unnecessary. Another commenter stated that the coding system frequently reflects differences in approach and technique, and that the equipment for analog and digital mammography are different enough to warrant separate reporting so we should not delete the G-codes. Some who supported continuation of the G-codes asked us to delay implementation as they were concerned that other payers would not have time to update their requirements by January 1, 2015. Another commenter applauded CMS's decision to delete the G-codes.

Response: In further consideration of this proposal, we discovered that while the CPT codes for diagnostic mammography apply to mammography, whether film or digital technology is used, the descriptor for the screening mammography CPT code specifically refers to film. In light of this and that fact that we anticipate revaluing these codes when we have the benefit of RUC recommendations for all codes in the family, we believe it is appropriate to continue to recognize both the CPT codes and the G-codes for mammography for CY 2015, as we consider appropriate valuations now that digital mammography is typical. Therefore, we are not finalizing our proposal to delete the G-codes. We are, however, making a change in the descriptors to make clear that the G0202, G0204, and G0206 are specific to 2-D mammography. These codes are to be reported with either G0279 or CPT code 77063 when mammography is furnished using 3-D mammography.

Comment: A commenter requested that CMS ensure reimbursement rates remain adequate to protect access for Medicare beneficiaries. Another commenter suggested that these changes could result in barriers to access for Medicare beneficiaries.

Response: We are strongly supportive of access to mammography for Medicare beneficiaries. As stated elsewhere in this final rule with comment period, we believe that accurate valuation incentivizes appropriate utilization of services.

After consideration of public comments, we are modifying our proposal as follows: We will include CPT codes 77055, 77056, and 77057 on the potentially misvalued codes list; we will continue to recognize G0202, G0204 and G0206 but will modify the

descriptors so that they are specific to 2-D digital mammography, and instead of using the digital values we will continue to use the CY 2014 work and PE RVUs to value the mammography CPT codes. We expect that the CPT Editorial Panel will consider the descriptor for screening mammography, CPT code 77057, in light of the prevailing use of digital mammography.

(5) Abdominal Aortic Aneurysm Ultrasound Screening (G0389)

When Medicare began paying for abdominal aortic aneurysm (AAA) ultrasound screening, HCPCS code G0389 (Ultrasound, B-scan and/or real time with image documentation; for abdominal aortic aneurysm (AAA) screening) in CY 2007, we set the RVUs at the same level as CPT code 76775 (Ultrasound, retroperitoneal (e.g., renal, aorta, nodes), B-scan and/or real time with image documentation; limited). We noted in the CY 2007 final rule with comment period that CPT code 76775 was used to report the service when furnished as a diagnostic test and that we believed the service reflected by G0389 used equivalent resources and work intensity to those contained in CPT code 76775 (71 FR 69664 through 69665).

In the CY 2014 proposed rule, we proposed to replace the ultrasound room included as a direct PE input for CPT code 76775 with a portable ultrasound unit based upon a RUC recommendation. Since the RVUs for G0389 were crosswalked from CPT code 76775, the proposed PE RVUs for G0389 in the CY 2014 proposed rule were reduced as a result of this change. However, we did not discuss the applicability of this change to G0389 in the preamble to the proposed rule, and did not receive any comments on G0389 in response to the proposed rule. We finalized the change to CPT code 76775 in the CY 2014 final rule with comment period and as a result, the PE RVUs for G0389 were also reduced.

We proposed G0389 as potentially misvalued in response to a stakeholder suggestion that the reduction in the RVUs for G0389 did not accurately reflect the resources involved in furnishing the service. We sought recommendations from the public and other stakeholders, including the RUC, regarding the appropriate work RVU, time, direct PE input, and malpractice risk factors that reflect the typical resources involved in furnishing the service.

Until we receive the information needed to re-value this service, we proposed to value this code using the same work and PE RVUs we used for CY

2013. We proposed MP RVUs based on the five-year review update process as described in section II.C of this final rule with comment period. We stated that we believe this valuation would ameliorate the effect of the CY 2014 reduction that resulted from the RVUs for G0389 being tied to those for another code while we assess appropriate valuation through our usual methodologies. Accordingly, we proposed a work RVU of 0.58 for G0389 and proposed to assign the 2013 PE RVUs until this procedure is reviewed.

Comment: Many commenters supported our proposal to include this service on the potentially misvalued codes list. Some commenters agreed that the crosswalk used to set rates for this service does not appear to be appropriate at this time, whether due to changes in the way the service is provided, or because the specialty mix has shifted, and suggested that it would be appropriate to establish a Category I CPT code for this service. Another commenter suggested that CMS consider crosswalking G0389 to CPT code 93979 (Duplex scan of aorta, inferior vena cava, iliac vasculature, or bypass grafts; unilateral or limited study). One commenter believed it was unnecessary to survey this code, but recommended that we instead maintain the general ultrasound room as a direct PE input and 2013 PE RVUs.

Response: We appreciate commenters' support for our proposal to include G0389 on the potentially misvalued codes list and are finalizing this proposal. We are finalizing this code as potentially misvalued in large part because we are unsure of the correct valuation. Therefore, we believe it is most appropriate to retain the 2013 inputs until we receive new recommendations, rather than making another change or retaining these inputs indefinitely as commenters suggested.

After consideration of comments received, we are finalizing our proposal to add G0389 to the potentially misvalued codes list, and to maintain the 2013 work and PE RVUs while we complete our review of the code. The MP RVUs will be calculated as discussion in section II.C. of this rule.

(6) Prostate Biopsy Codes—(HCPCS Codes G0416, G0417, G0418, and G0419)

For CY 2014, we modified the code descriptors of G0416 through G0419 so that these codes could be used for any method of prostate needle biopsy services, rather than only for prostate saturation biopsies. The CY 2014 descriptions are:

- G0416 (Surgical pathology, gross and microscopic examination for prostate needle biopsies, any method; 10–20 specimens).
- G0417 (Surgical pathology, gross and microscopic examination for prostate needle biopsies, any method; 21–40 specimens).
- G0418 (Surgical pathology, gross and microscopic examination for prostate needle biopsies, any method; 41–60 specimens).
- G0419 (Surgical pathology, gross and microscopic examination for prostate needle biopsies, any method; greater than 60 specimens).

Subsequently, we have discussed prostate biopsies with stakeholders, and reviewed medical literature and Medicare claims data in considering how best to code and value prostate biopsy pathology services. After considering these discussions and information, we believed it would be appropriate to use only one code to report prostate biopsy pathology services. Therefore, we proposed to revise the descriptor for G0416 to define the service regardless of the number of specimens, and to delete codes G0417, G0418, and G0419. We believe that using G0416 to report all prostate biopsy pathology services, regardless of the number of specimens, would simplify the coding and mitigate overutilization incentives. Given the infrequency with which G0417, G0418, and G0419 are used, we did not believe that this was a significant change.

Based on our review of medical literature and examination of Medicare claims data, we indicated that we believe that the typical number of specimens evaluated for prostate biopsies is between 10 and 12. Since G0416 currently is used for between 10 and 12 specimens, we proposed to use the existing values for G0416 for CY 2015, since the RVUs for this service were established based on similar assumptions.

In addition, we proposed G0416 as a potentially misvalued code for CY 2015 and sought public comment on the appropriate work RVUs, work time, and direct PE inputs.

Comment: One commenter supported the elimination of the G-codes as a means of simplifying coding requirements, but other commenters opposed our proposal to consolidate the coding into G0416, disagreeing that this would help establish “straightforward coding and maintain accurate payment” as suggested in the proposed rule. Some commenters suggested that we retain the current codes so that biopsy procedures requiring more than 10 specimens can be reimbursed accurately, and indicated

that consolidating the coding would further confuse physicians and their staff who have not yet adapted to the CY 2014 coding changes for these G-codes. Other commenters asserted that these changes threaten to undermine access to high quality pathology services. Commenters also stated that the decision to furnish more extensive pathological analysis is not at the discretion of the pathologist, and the pathologist should not be penalized when he or she receives more cores to analyze.

With respect to our proposing G0416 as potentially misvalued, commenters stated that the recent change to these codes has already been confusing and suggests that there is not a clear understanding of what these codes represent, thus making an assessment of their valuation difficult. Commenters further stated that it is unreasonable to consider this a misvalued code when the payment is already 30 percent below what they think it should be, and that CMS has failed to provide justification for why it is potentially misvalued.

The RUC and others suggested that it would be most accurate to utilize CPT code 88305 (Level IV—surgical pathology, gross and microscopic examination) for the reporting of prostate biopsies and to allow the reporting of multiple units. Given the additional granularity and scrutiny given to CPT code 88305 in the CY 2014 final rule, the commenters indicated that they believe that the agency’s intent to establish straightforward coding and accurate payment for these services would be realized with this approach.

Response: Given that the typical analysis of prostate biopsy specimens differs significantly from the typical analyses reported using CPT code 88305, as regards the number of blocks used to process the specimen and thus the amount of work involved, we believe that by distinguishing prostate biopsies from other types of biopsies results in more accurate pricing for prostate biopsies. Since CPT code 88305 was revalued with the understanding that prostate biopsies are billed separately, we believe that allowing CPT code 88305 to be reported in multiple units for prostate biopsies would account for significantly more resources than is appropriate. With respect to the concern about higher numbers of specimens, we note that our claims data on the G-codes shows that the vast majority of the claims used G0416, rather than any of the G-codes for greater numbers of specimens.

After consideration of comments received, we are finalizing our proposal to include G0416 on the potentially

misvalued codes list, to modify the descriptor to reflect all prostate biopsies, and to maintain the current value until we receive and review information and recommendations from the RUC. We are also finalizing our proposal to delete codes G0417, G0418, and G0419.

(7) Obesity Behavioral Group Counseling—GXXX2 and GXXX3

Pursuant to section 1861(ddd) of the Act, we added coverage for a new preventive benefit, Intensive Behavioral Therapy for Obesity, effective November 29, 2011, and created HCPCS code G0447 (Face-to-face behavioral counseling for obesity, 15 minutes) for reporting and payment of individual behavioral counseling for obesity. Coverage requirements specific to this service are delineated in the Medicare National Coverage Determinations Manual, Pub. 100–03, Chapter 1, Section 210, available at http://www.cms.gov/manuals/downloads/ncd103c1_Part4.pdf.

It was brought to our attention that behavioral counseling for obesity is sometimes furnished in group sessions, and questions were raised about whether group sessions could be billed using HCPCS code G0447. To improve payment accuracy, we proposed to create two new HCPCS codes for the reporting and payment of group behavioral counseling for obesity. Specifically, we proposed to create GXXX2 (Face-to-face behavioral counseling for obesity, group (2–4), 30 minutes) and GXXX3 (Face-to-face behavioral counseling for obesity, group (5–10), 30 minutes). We indicated that the coverage requirements for these services would remain in place, as described in the National Coverage Determination for Intensive Behavioral Therapy for Obesity cited above. The practitioner furnishing these services would report the relevant group code for each beneficiary participating in a group therapy session.

Since we believed that the face-to-face behavioral counseling for obesity services described by GXXX2 and GXXX3 would require similar per minute work and intensity as HCPCS code G0447, we proposed work RVUs of 0.23 and 0.10 for HCPCS codes GXXX2 and GXXX3, with work times of 8 minutes and 3 minutes respectively. Since the services described by GXXX2 and GXXX3 would be billed per beneficiary receiving the service, the work RVUs and work time that we proposed for these codes were based upon the assumed typical number of beneficiaries per session, 4 and 9, respectively. Accordingly, we proposed

a work RVU of 0.23 with a work time of 8 minutes for GXXX2 and a work RVU of 0.10 with a work time of 3 minutes for GXXX3. We proposed to use the direct PE inputs for GXXX2 and GXXX3 currently included for G0447 prorated to account for the differences in time and number of beneficiaries, and to crosswalk the malpractice risk factor from HCPCS code G0447 to both HCPCS codes GXXX2 and GXXX3, as we believe the same specialty mix will furnish these services. We requested public comment on the proposed values for HCPCS codes GXXX2 and GXXX3.

Comment: Commenters generally supported our proposal to establish a separate payment mechanism for obesity behavioral group counseling services, but raised several concerns regarding the coding structure and valuation of these services. Commenters stated that the work times were inaccurate, requested that the service be valued based on a smaller number of typical group participants, and questioned the need for two G-codes when group counseling services under the PFS are generally billed with a single G-code. A commenter also stated that the lower payment for larger groups will create disincentives for furnishing this service except when there is a full 10-person group, which could limit access. Commenters suggested that CMS only finalize a single G-code for group counseling for intensive behavioral therapy for obesity, and crosswalk the work RVU and work time for this service from the Medical Nutrition Therapy (MNT) group code.

Response: We appreciate commenters' support for our proposal to provide new codes for group obesity counseling services. After reviewing the comments, we agree that it is reasonable to create a single code for group obesity counseling and crosswalk the work RVU and work time from the MNT group code. The individual code for intensive obesity behavioral therapy and the individual MNT code are valued the same, so in the absence of evidence that group composition is different, we believe it makes sense to use the same values. Therefore, we will crosswalk the work RVU of 0.25 and the work time of 10 minutes to a single new G-code for group obesity counseling, G0473 (Face-to-face behavioral counseling for obesity, group (2–10), 30 minutes).

4. Improving the Valuation and Coding of the Global Package

a. Overview

Since the inception of the PFS, we have valued and paid for certain services, such as surgery, as part of

global packages that include the procedure and the services typically furnished in the periods immediately before and after the procedure (56 FR 59502). For each of these codes (usually referred to as global surgery codes), we establish a single PFS payment that includes payment for particular services that we assume to be typically furnished during the established global period.

There are three primary categories of global packages that are labeled based on the number of post-operative days included in the global period: 0-day; 10-day; and 90-day. The 0-day global codes include the surgical procedure and the pre-operative and post-operative physicians' services on the day of the procedure, including visits related to the service. The 10-day global codes include these services and, in addition, visits related to the procedure during the 10 days following the procedure. The 90-day global codes include the same services as the 0-day global codes plus the pre-operative services furnished one day prior to the procedure and post-operative services during the 90 days immediately following the day of the procedure.

Section 40.1 of the Claims Processing Manual (Pub. 100–04, Chapter 12 Physician/Nonphysician Practitioners) defines the global surgical package to include the following services when furnished during the global period:

- **Preoperative Visits**—Preoperative visits after the decision is made to operate beginning with the day before the day of surgery for major procedures and the day of surgery for minor procedures;
- **Intra-operative Services**—Intra-operative services that are normally a usual and necessary part of a surgical procedure;
- **Complications Following Surgery**—All additional medical or surgical services required of the surgeon during the postoperative period of the surgery because of complications that do not require additional trips to the operating room;
- **Postoperative Visits**—Follow-up visits during the postoperative period of the surgery that are related to recovery from the surgery;
- **Postsurgical Pain Management**—By the surgeon;
- **Supplies**—Except for those identified as exclusions; and
- **Miscellaneous Services**—Items such as dressing changes; local incisional care; removal of operative pack; removal of cutaneous sutures and staples, lines, wires, tubes, drains, casts, and splints; insertion, irrigation and removal of urinary catheters, routine peripheral intravenous lines, nasogastric and rectal

tubes; and changes and removal of tracheostomy tubes.

b. Concerns With the 10- and 90-Day Global Packages

CMS supports bundled payments as a mechanism to incentivize high-quality, efficient care. Although on the surface, the PFS global codes appear to function as bundled payments similar to those Medicare uses to make single payments for multiple services to hospitals under the inpatient and outpatient prospective payment systems, the practical reality is that these global codes function significantly differently than other bundled payments. First, the global surgical codes were established several decades ago when surgical follow-up care was far more homogenous than today. Today, there is more diversity in the kind of procedures covered by global periods, the settings in which the procedures and the follow-up care are furnished, the health care delivery system and business arrangements used by Medicare practitioners, and the care needs of Medicare beneficiaries. Despite these changes, the basic structures of the global surgery packages are the same as the packages that existed prior to the creation of the resource-based relative value system in 1992. Another significant difference between this and other typical models of bundled payments is that the payment rates for the global surgery packages are not updated regularly based on any reporting of the actual costs of patient care. For example, the hospital inpatient and outpatient prospective payment systems (the IPPS and OPPOS, respectively) derive payment rates from hospital cost and charge data reported through annual Medicare hospital cost reports and the most recent year of claims data available for an inpatient stay or primary outpatient service.

Because payment rates are based on consistently updated data, over time, payment rates adjust to reflect the average resource costs of current practice. Similarly, many of the new demonstration and innovation models track costs and make adjustments to payments. Another significant difference is that payment for the PFS global packages relies on valuing the combined services together. This means that there are no separate PFS values established for the procedures or the follow-up care, making it difficult to estimate the costs of the individual global code component services.

In the following paragraphs, we address a series of concerns regarding the accuracy of payment for 10- and 90-day global codes, including: The fundamental difficulties in establishing

appropriate relative values for these packages, the potential inaccuracies in the current information used to price global codes, the limitations on appropriate pricing in the future, the potential for global packages to create unwarranted payment differentials among specialties, the possibility that the current codes are incompatible with current medical practice, and the potential for these codes to present obstacles to the adoption of new payment models.

Concerns such as these commonly arise when developing payment mechanisms, for example fee-for-service payment rates, single payments for multiple services, or payment for episodes of care over a period of time. However, in the case of the post-operative portion of the 10- and 90-day global codes, we believe that together with certain unique aspects of PFS rate setting methodology, these concerns create substantial barriers to accurate valuation of these services relative to other PFS services.

(1) Fundamental Limitations in the Appropriate Valuation of the Global Packages With Post-Operative Days

In general, we face many challenges in valuing PFS services as accurately as possible. However, the unique nature of global surgery packages with 10- and 90-day post-operative periods presents additional challenges distinct from those presented in valuing other PFS services. Our valuation methodology for PFS services generally relies on assumptions regarding the resources involved in furnishing the “typical case” for each individual service unlike other payment systems that rely on actual data on the costs of furnishing services. Consistent with this valuation methodology, the RVUs for a global code should reflect the typical number and level of E/M services furnished in connection with the procedure. However, it is much easier to maintain relativity among services that are valued on this basis when each of the services is described by codes of similar unit sizes. In other words, because codes with long post-operative periods include such a large number of services, any variations between the “typical” resource costs used to value the service and the actual resource costs associated with particular services are multiplied. The effects of this problem can be two-fold, skewing the accuracy of both the RVUs for individual global codes and the Medicare payment made to individual practitioners. The RVUs of the individual global service codes are skewed whenever there is any inaccuracy in the assumption of the

typical number or kind of services in the post-operative periods. This inaccuracy has a greater impact than inaccuracies in assumptions for non-global codes because it affects a greater number of service units over a period of time than for individually priced services. Furthermore, in contrast to prospective payment systems, such inaccuracies under the PFS are not corrected over time through a ratesetting process that makes year-to-year adjustments based on data on actual costs. For example, if a 90-day global code is valued based on an assumption or survey response that ten post-operative visits is typical, but practitioners reporting the code in fact typically only furnish six visits, then the resource assumptions are overestimated by the value of the four visits multiplied by the number of the times the procedure code is reported. In contrast, when our assumptions are incorrect about the typical resources involved in furnishing a PFS code that describes a single service, any inaccuracy in the RVUs is limited to the difference between the resource costs assumed for the typical service and the actual resource costs in furnishing one individual service. Such a variation between the assumptions used in calculating payment rates and the actual resource costs could be corrected if the payments for packaged services were updated regularly using data on actual services furnished. Medicare’s prospective payment systems have more mechanisms in place than the PFS does to adjust over time for such variation. To make adjustments to the RVUs to account for inaccurate assumptions under the current PFS methodology, the global surgery code would need to be identified as potentially misvalued, survey data would have to reflect an accurate account of the number and level of typical post-operative visits, and we (with or without a corresponding recommendation from the RUC or others) would have to implement a change in RVUs based on the change in the number and level of visits to reflect the typical service.

These amplified inaccuracies may also occur whenever Medicare pays an individual practitioner reporting a 10- or 90-day global code. Practitioners may furnish a wide range of post-operative services to individual Medicare beneficiaries, depending on individual patient needs, changes in medical practice, and dynamic business models. Due to the way the 10- and 90-day global codes are constructed, the number and level of services included for purposes of calculating the payment for these services may vary greatly from

the number and level of services that are actually furnished in any particular case. In contrast, the variation between the “typical” and the actual resource cost for the practitioner reporting an individually valued PFS service is constrained because the practitioner is only reporting and being paid for a specific service furnished on a particular date.

For most PFS services, any difference between the “typical” case on which RVUs are based and the actual case for a particular service is limited to the variation between the resources assumed to be involved in furnishing the typical case and the actual resources involved in furnishing the single specific service. When the global surgical package includes more or a higher level of E/M services than are actually furnished in the typical post-operative period, the Medicare payment is based on an overestimate of the quantity or kind of services furnished, not merely an overestimation of the resources involved in furnishing an individual service. The converse is true if the RVUs for the global surgical package are based on fewer or a lower level of services than are typically furnished for a particular code.

(2) Questions Regarding Accuracy of Current Assumptions

In previous rulemaking (77 FR 68911 through 68913), we acknowledged evidence suggesting that the values included in the post-operative period for global codes may not reflect the typical number and level of post-operative E/M visits actually furnished.

In 2005, the OIG examined whether global surgical packages are appropriately valued. In its report on eye and ocular surgeries, “National Review of Evaluation and Management Services Included in Eye and Ocular Adnexa Global Surgery Fees for Calendar Year 2005” (A-05-07-00077), the OIG reviewed a sample of 300 eye and ocular surgeries, and counted the actual number of face-to-face services recorded in the patients’ medical records to establish whether and, if so, how many post-operative E/M services were furnished by the surgeons. For about two-thirds of the claims sampled by the OIG, surgeons furnished fewer E/M services in the post-operative period than were included in the global surgical package payment for each procedure. A small percentage of the surgeons furnished more E/M services than were included in the global surgical package payment. The OIG identified the number of face-to-face services recorded in the medical record, but did not review the medical necessity

of the surgeries or the related E/M services. The OIG concluded that the RVUs for these global surgical packages are too high because they include a higher number of E/M services than typically are furnished within the global period for the reviewed procedures.

Following that report, the OIG continued to investigate E/M services furnished during global surgical periods. In May 2012, the OIG published a report entitled “Musculoskeletal Global Surgery Fees Often Did Not Reflect the Number of Evaluation and Management Services Provided” (A–05–09–00053). For this investigation, the OIG sampled 300 musculoskeletal global surgeries and again found that, for the majority of sampled surgeries, physicians furnished fewer E/M services than were included as part of the global period payment for that service. Once again, a small percentage of surgeons furnished more E/M services than were included in the global surgical package payment. The OIG concluded that the RVUs for these global surgical packages are too high because they include a higher number of E/M services than typically are furnished within the global period for the reviewed procedures.

In both reports, the OIG recommended that we adjust the number of E/M services identified with the studied global surgical payments to reflect the number of E/M services that are actually being furnished. However, since it is not necessary under our current global surgery payment policy for a surgeon to report the individual E/M services actually furnished during the global surgical period, we do not have objective data upon which to assess whether the RVUs for global period surgical services reflect the typical number or level of E/M services that are furnished. In the CY 2013 PFS proposed rule (77 FR 44738), we previously sought public comments on collecting these data. As summarized in the CY 2013 PFS final rule (77 FR 68913) we did not discover a consensus among stakeholders regarding either the most appropriate means to gather the data, or the need for, or the appropriateness of using such data in valuing these services. In response to our comment solicitation, some commenters urged us to accept the RUC survey data as accurate in spite of the OIG reports and other concerns that have been expressed regarding whether the visits included in the global periods reflected the typical case. Others suggested that we should conduct new surveys using the RUC approach or that we should mine hospital data to identify the typical number of visits furnished. Some

comments suggested eliminating the 10- and 90-day global codes.

(3) Limitations on Appropriate Future Valuations of 10- and 90-Day Global Codes

Historically, our attempts to adjust RVUs for global services based on changes in the typical resource costs (especially with regard to site of service assumptions or changes to the number of post-surgery visits) have been difficult and controversial. At least in part, this is because the relationship between the work RVUs for the 10- and 90-day global codes (which includes the work RVU associated with the procedure itself) and the number of included post-operative visits in the existing values is not always clear. Some services with global periods have been valued by adding the work RVU of the surgical procedure and all pre- and post-operative E/M services included in the global period. However, in other cases, as many stakeholders have noted, the total work RVUs for surgical procedures and post-operative visits in global periods are estimated as a single value without any explicit correlation to the time and intensity values for the individual service components. Although we would welcome more objective information to improve our determination of the “typical” case, we believe that even if we engaged in the collection of better data on the number and level of E/M services typically furnished during the global periods for global surgery services, the valuation of individual codes with post-operative periods would not be straightforward. Furthermore, we believe it would be important to frequently update the data on the number and level of visits furnished during the post-operative periods in order to account for any changes in the patient population, medical practice, or business arrangements. Practitioners paid through the PFS do not report such data.

(4) Unwarranted Payment Disparities

Subsequent to our last comment solicitation regarding the valuation of the post-operative periods (77 FR 68911 through 68913), some stakeholders have raised concerns that global surgery packages contribute to unwarranted payment disparities between practitioners who do and do not furnish these services. These stakeholders have addressed several ways the 10- and 90-day global packages may contribute to unwarranted payment disparities.

The stakeholders noted that, through the global surgery packages, Medicare pays practitioners who furnish E/M services during post-surgery periods

regardless of whether the services are actually furnished, while practitioners who do not furnish global procedures with post-operative visits are only paid for E/M services that are actually furnished. In some cases, it is possible that the practitioner furnishing the global surgery procedure may not furnish any post-operative visits. Although we have policies to address the situation when post-operative care is transferred from one practitioner to another, the beneficiary might simply choose to seek care from another practitioner without a formal transfer of care. The other practitioner would then bill Medicare separately for E/M services for which payment was included in the global payment to the original practitioner. Those services would not have been separately billable if furnished by the original practitioner.

These circumstances can lead to unwarranted payment differences, allowing some practitioners to receive payment for fewer services than reflected in the Medicare payment. Practitioners who do not furnish global surgery services bill and are paid only for each individual service furnished. When global surgery values are based on inaccurate assumptions about the typical services furnished in the post-operative periods, these payment disparities can contribute to differences in aggregate RVUs across specialties. Since the RVUs are intended to reflect differences in the relative resource costs involved in furnishing a service, any disparity between assumed and actual costs results not only in paying some practitioners for some services that are not furnished, it also skews relativity between specialties.

Stakeholders have also pointed out that payment disparities can arise because E/M services reflected in global periods generally include higher PE values than the same services when billed separately. The difference in PE values between separately billed visits and those included in global packages result primarily from two factors that are both inherent in the PFS pricing methodology.

First, there is a different mix of PE inputs (clinical labor/supplies/equipment) included in the direct PE inputs for a global period E/M service and a separately billed E/M service. For example, the clinical labor inputs for separately reportable E/M codes includes a staff blend listed as “RN/LPN/MTA” (L037D) and priced at \$0.37 per minute. Instead of this input, some codes with post-operative visits include the staff type “RN” (L051A) priced at a higher rate of \$0.51 per minute. For these codes, the higher resource cost

may accurately reflect the typical resource costs associated with those particular visits. However, the different direct PE inputs may drive unwarranted payment disparities among specialties who report global surgery codes with post-operative periods and those that do not. The only way to correct these potential discrepancies under the current system, which result from the specialty-based differences in resource costs, would be to include standard direct PE inputs for these services regardless of whether or not the standard inputs are typical for the specialties furnishing the services.

Second, the indirect PE allocated to the E/M visits included in global surgery codes is higher than that allocated to separately furnished E/M visits. This occurs because the range of specialties furnishing a particular global service is generally not as broad as the range of specialties that report separate individual E/M services. Since the specialty mix for a service is a key factor in determining the allocation of indirect PE to each code, a higher amount of indirect PE can be allocated to the E/M services that are valued as part of the global surgery codes than to the individual E/M codes. Practitioners who use E/M codes to report visits separately are paid based on PE RVUs that reflect the amount of indirect PE allocated across a wide range of specialties, which has the tendency to lower the amount of indirect PE. For practitioners who are paid for visits primarily through post-operative periods, indirect PE is generally allocated with greater specificity. Two significant steps would be required to alleviate the impact of this disparity. First, we would have to identify the exact mathematical relationship between the work RVU and the number and level of post-operative visits for each global code; and second, we would have to propose a significant alteration of the PE methodology in order to allocate indirect PE that does not correlate to the specialties reporting the code in the Medicare claims data.

Furthermore, stakeholders have pointed out that the PE RVUs for codes with 10- or 90-day post-operative periods reflect the assumption that all outpatient visits occur in the higher-paid non-facility office setting, when many of these visits are likely to be furnished in provider-based departments, which would be paid at the lower, PFS facility rate if they were billable separately. As we note elsewhere in this final rule with comment period, we do not have data on the volume of physicians' services furnished in provider-based departments, but public information

suggests that it is not insignificant and that it is growing. When these services are paid as part of a global package, there is no adjustment made based on the site of service. Therefore, even though the PFS payment for services furnished in post-operative global periods might include clinical labor, disposable supply, and medical equipment costs (and additional indirect PE allocation) that are incurred by the facility and not the practitioner reporting the service, the RVUs for global codes reflect all of these costs associated with the visits.

(5) Incompatibility of Current Packages With Current Practice and Unreliability of RVUs for Use in New Payment Models

In addition to these issues, the 10- and 90-day global periods reflect a long-established but no longer exclusive model of post-operative care that assumes the same practitioner who furnishes the procedure typically furnishes the follow-up visits related to that procedure. In many cases, we believe that models of post-operative care are increasingly heterogeneous, particularly given the overall shift of patient care to larger practices or team-based environments.

We believe that RVUs used to establish PFS payments are likely to serve as critical building blocks to developing, testing, and implementing a number of new payment models, including those that focus on bundled payments to practitioners or payments for episodes of care. Therefore, we believe it is critical for us to ensure that the PFS RVUs accurately reflect the resource costs for individual PFS services instead of reflecting potentially skewed assumptions regarding the number of services furnished over a long period of time in the "typical" case. To the extent that the 10- and 90-day global periods reflect inaccurate assumptions regarding resource costs associated with individual PFS services, we believe they are likely to be obstacles to a wide range of potential improvements to PFS payments, including the potential incorporation of payment bundling designed to foster efficiency and quality care for Medicare beneficiaries.

c. Proposed Transformation of 10- and 90-Day Global Packages Into 0-Day Global Packages

Although we have marginally addressed some of the concerns noted above with global packages in previous rulemaking, we do not believe that we have made significant progress in addressing the fundamental issues with

the 10- and 90-day post-operative global packages. In the context of the misvalued code initiative, we believe it is critical for the RVUs used to develop PFS payment rates reflect the most accurate resource costs associated with PFS services. Based on the issues discussed above, we do not believe we can effectively address the issues inherent in establishing values for the 10- and 90-day global packages under our existing methodologies and with available data. As such, we do not believe that maintaining the post-operative 10- and 90-day global periods is compatible with our continued interest in using more objective data in the valuation of PFS services and accurately valuing services relative to each other. Because the typical number and level of post-operative visits during global periods may vary greatly across Medicare practitioners and beneficiaries, we believe that continued valuation and payment of these face-to-face services as a multi-day package may skew relativity and create unwarranted payment disparities within PFS fee-for-service payment. We also believe that the resource based valuation of individual physicians' services will continue to serve as a critical foundation for Medicare payment to physicians, whether through the current PFS or in any number of new payment models. Therefore, we believe it is critical that the RVUs under the PFS be based as closely and accurately as possible on the actual resources involved in furnishing the typical occurrence of specific services.

To address the issues discussed above, we proposed to retain global bundles for surgical services, but to refine bundles by transforming over several years all 10- and 90-day global codes to 0-day global codes. Medically reasonable and necessary visits would be billed separately during the pre- and post-operative periods outside of the day of the surgical procedure. We propose to make this transition for current 10-day global codes in CY 2017 and for the current 90-day global codes in CY 2018, pending the availability of data on which to base updated values for the global codes.

We believe that transforming all 10- and 90-day global codes to 0-day global codes would:

- Increase the accuracy of PFS payment by setting payment rates for individual services based more closely upon the typical resources used in furnishing the procedures;
- Avoid potentially duplicative or unwarranted payments when a beneficiary receives post-operative care

from a different practitioner during the global period;

- Eliminate disparities between the payment for E/M services in global periods and those furnished individually;
- Maintain the same-day packaging of pre- and post-operative physicians' services in the 0-day global; and
- Facilitate availability of more accurate data for new payment models and quality research.

As we transition these codes, we would need to establish RVUs that reflect the change in the global period for all the codes currently valued as 10- and 90-day global surgery services. We sought assistance from stakeholders on various aspects of this task. Prior to implementing these changes, we intend to gather objective data on the number of E/M and other services furnished during the current post-operative periods and use those data to inform both the valuation of particular services and the overall budget neutrality adjustments required to implement this proposal. We sought comment on the most efficient means of acquiring accurate data regarding the number of visits and other services actually being furnished by the practitioner during the current post-operative periods. For all the reasons stated above, we do not believe that survey data reflecting assumptions of the "typical case" meets the standards required to measure the resource costs of the wide range of services furnished during the post-operative periods. We acknowledge that collecting information on these services through claims submission may be the best approach, and we would propose such a collection through future rulemaking. However, we are also interested in alternatives. For example, we sought information on the extent to which individual practitioners or practices may currently maintain their own data on services furnished during the post-operative period, and how we might collect and objectively evaluate that data.

We also sought comment on the best means to ensure that allowing separate payment of E/M visits during post-operative periods does not incentivize otherwise unnecessary office visits during post-operative periods. If we adopt this proposal, we intend to monitor any changes in the utilization of E/M visits following its implementation but we also solicited comment on potential payment policies that will mitigate such a change in behavior.

In developing this proposal, we considered several alternatives to the transformation of all global codes to 0-

day global codes. First, we again considered the possibility of gathering data and using the data to revalue the 10- and 90-day global codes. While this option would have maintained the status quo in terms of reporting services, it would have required much of the same effort as this proposal without alleviating many of the problems associated with the 10- and 90-day global periods. For example, collecting accurate data would allow for more accurate estimates of the number and kind of visits included in the post-operative periods at the time of the survey. However, this alternative approach would only mitigate part of the potential for unwarranted payment disparities. For example, the values for the visits in the global codes would continue to include different amounts of PE RVUs than separately reportable visits and would continue to provide incentives to some practitioners to minimize patient visits. Additionally, it would not address the changes in practice patterns that we believe have been occurring whereby the physician furnishing the procedure is not necessarily the same physician providing the post-procedure follow up.

This alternative option would also rest extensively on the effectiveness of using the new data to revalue the codes accurately. Given the unclear relationship between the assigned work RVUs and the post-operative visits across all of these services, incorporating objective data on the number of visits to adjust work RVUs would still necessitate extensive review of individual codes or families of codes by CMS and stakeholders, including the RUC. We believe the investment of resources for such an effort would be better made to solve a broader range of problems.

We also considered other possibilities, such as altering our PE methodology to ensure that the PE inputs and indirect PE for visits in the global period were valued the same as separately reportable E/M codes or requiring reporting of the visits for all 10- and 90-day global services while maintaining the 10- and 90-day global period payment rates. However, we believe this option would require all of the same effort by practitioners, CMS, and other stakeholders without alleviating most of the problems addressed in the preceding paragraphs.

We also considered maintaining the status quo and identifying each of the 10- and 90-day global codes as potentially misvalued through our potentially misvalued code process for review as 10- and 90-day globals. Inappropriate valuations of these

services has a major effect on the fee schedule due to the percentage of PFS dollars paid through 10- and 90-day global codes (3 percent and 11 percent, respectively), and thus, valuing them appropriately is critical to appropriate valuation and relativity throughout the PFS. Through the individual review approach, we could review the appropriateness of the global period and the accurate number of visits for each service. Yet revaluing all 3,000 global surgery codes through the potentially misvalued codes approach would not address many of the problems identified above. Unless such an effort was combined with changes in the PE methodology, it would only partially address the valuation and accuracy issues and would leave all the other issues unresolved. Moreover, the valuation and accuracy issues that could be addressed through this approach would rapidly be out of date as medical practice continues to change. Therefore, such an approach would be only partially effective and would impede our ability to address other potentially misvalued codes.

We sought stakeholder input on an accurate and efficient means to revalue or adjust the work RVUs for the current 10- and 90-day global codes to reflect the typical resources involved in furnishing the services including both the pre- and post-operative care on the day of the procedure. We believe that collecting data on the number and level of post-operative visits furnished by the practitioner reporting current 10- and 90-day global codes will be important to ensuring work RVU relativity across these services. We also believe that these data will be important to determine the relationship between current work RVUs and current number of post-operative visits, within categories of codes and code families. However, we believe that once we collect those data, there is a wide range of possible approaches to the revaluation of the large number of individual global services, some of which may deviate from current processes like those undertaken by the RUC. To date, the potentially misvalued code initiative has focused on several hundred, generally high-volume codes per year. This proposal requires revaluing a larger number of codes over a shorter period of time and includes many services with relatively low volume in the Medicare population. Given these circumstances, it does not seem practical to survey time and intensity information on each of these procedures. Absent any new survey data regarding the procedures themselves,

we believe that data regarding the number and level of post-service office visits can be used in conjunction with other methods of valuation, such as:

- Using the current potentially misvalued code process to identify and value the relatively small number of codes that represent the majority of the volume of services that are currently reported with codes with post-operative periods, and then adjusting the aggregate RVUs to account for the number of visits and using magnitude estimation to value the remaining services in the family.

- Valuing one code within a family through the current valuation process and then using magnitude estimation to value the remaining services in the family.

- Surveying a sample of codes across all procedures to create an index that could be used to value the remaining codes.

Although we believe these are plausible options for the revaluation of these services, we believed there may be others. Therefore, we sought input on the best approach to achieve this proposed transition from 10- and 90-day, to 0-day global periods, including the timing of the changes, the means for revaluation, and the most effective and least burdensome means to collect objective, representative data regarding the actual number of visits currently furnished in the post-operative global periods. We also solicited comment on whether the effective date for the transition to 0-day global periods should be staggered across families of codes or other categories. For example, while we proposed to transition 10-day global periods in 2017 and 90-day global periods in 2018, we solicited comment on whether we should consider implementing the transition more or less quickly and over one or several years. We also solicited comment regarding the appropriate valuation of new, revised, or potentially misvalued 10- or 90-day global codes before implementation of this proposal.

We received many comments regarding the proposed transition to 0-day global packages. Many commenters expressed support or opposition to the proposal. Some commenters offered direct responses to the topics for which we specifically sought comment, while others raised questions regarding how the transition would be implemented. In the following paragraphs, we summarize and respond to these comments.

Comment: Several commenters supported the proposal, including commenters representing several medical specialty societies and several health systems. Many of these

commenters agreed with the reasons presented in the proposal. These commenters agreed that the current structure of the global surgery codes prevents CMS from accurately valuing and paying for these services, even if CMS had necessary visit data available. Many commenters agreed that the current arrangement may lead to unwarranted payment disparities and that the current packages have not evolved with changes in practice and because of this, likely provide unreliable building blocks for new payment methodologies.

In agreeing with the proposal, MedPAC stated that it “is essential that the individual services that make up a bundle have accurate values and that there is a mechanism to ensure that the services that are part of the bundle are not paid separately (unbundling). Otherwise, the payment rate for the entire bundle will be inaccurate.” MedPAC urged CMS to finalize this proposal and plan to use the more accurate valuations to create more accurate bundles in the future.

Response: We appreciate the commenters’ support for the proposal, and agree that there are many reasons why the current construction of the global surgery packages is difficult to reconcile with accurate valuation of individual services within the current payment construct of the PFS. We agree that achieving the agency’s goal of greater bundling requires accurate valuation of component services in a surgical procedure.

Comment: Some commenters, including several of those representing specialty societies, urged CMS to postpone finalization of the proposal pending the report of stakeholder efforts to conduct a comprehensive analysis of the effect it would have on the provision of surgical care, surgical patients, and the surgeons who care for them.

Response: We share stakeholders’ concerns regarding the potential impact of the change on Medicare beneficiaries and practitioners. However, based upon our analysis and the information that stakeholders have provided, we believe delaying the proposal to further study the problems is not warranted given the significant concerns that have been raised with the current construction of the global surgery packages. Instead, as we articulated in making the proposal, we anticipate that further analysis by stakeholders will contribute to implementing the transition in a manner that accurately values and pays for PFS services. We believe that accurate valuation of services furnished to Medicare beneficiaries is overwhelmingly in the best interest of

both beneficiaries and those who care for them.

Comment: We received several comments from commenters who opposed our proposal, and in general these commenters shared the concerns of those who urged a delay in finalizing or implementing the proposal. In addition, some commenters who opposed the proposal disputed our contention that the global periods contribute to unwarranted payment disparities, saying that the increased direct and indirect PE and MP RVUs for E/M services furnished in the global surgical post-operative periods accurately account for the increased PE and MP costs of practitioners who furnish these services relative to practitioners who typically furnish separately reportable E/M services.

Response: Just as we do not agree that we should delay addressing significant problems with valuations while we further study the issues, we do not believe these same issues raised by commenters opposing the proposal are impediments to implementation. The issues relating to valuation of global period E/M services using our PE methodology are just one of several important considerations that led us to propose transforming 10- and 90-day global services to 0-day global packages. We continue to believe the proposed transformation to 0-day global packages is a simple and immediate step to improve the valuation of the various services included in surgical care. However, Medicare remains committed to bundled payment as a mechanism for delivery system reform and we will continue to explore the best way to bundle surgical services, including alternatives to the 0-day global surgical bundle.

Comment: Many commenters who opposed the proposal addressed valuation problems that would exist if the proposal were implemented. Some stated that, were CMS to finalize the proposal to pay for post-surgical E/Ms using the same codes, the PE and MP RVUs for the services would be artificially reduced because the data from other specialties would be incorporated. These commenters suggested CMS should consider how to maintain the current differences in payment for these services even if the proposal were finalized. Some commenters suggested that CMS would need to account for the additional practice expense and malpractice costs for post-operative surgical visits.

Response: We develop and establish work, PE, and MP RVUs for specific services to reflect the relative resource costs involved in furnishing the typical

PFS service. In developing the proposal, we noted that by including a significant number of E/Ms in the global periods for surgical services, the PFS ratesetting methodology distinguishes these services from other E/Ms for purposes of developing PE and MP RVUs, potentially to the advantage of particular specialties with higher PE and MP RVUs. In contrast, the work RVUs for individual, separately billed E/M services furnished, for example, by primary care practitioners are valued more generally as individual services, and values are not maintained separately from the work RVUs for E/Ms furnished by other practitioners. Therefore, we do not agree with commenters that Medicare should establish higher PE and MP values for E/M services furnished in the post-surgical period than for other E/M services.

Comment: Several commenters suggested that CMS should not use the OIG reports to generalize its concerns about the provision of surgical care, because the OIG reports represent only a small sample of observations of specific procedures and specialties. Other commenters suggested that the OIG methodology might be flawed because, since CMS does not require documentation of post-operative visits, many practitioners may not document such visits in the medical record.

Response: We do not have any reason to believe that the OIG findings on the global surgical service packages furnished by particular specialties that the OIG reviewed are not generalizable to other global surgery services. Nor did the commenters provide any evidence that the OIG conclusions are likely to be less accurate than the survey estimates that CMS uses to value the services. Finally, having an incorrect number of postoperative visits is only one of the many valuation problems that have been identified for global surgical packages. Additionally, we find the suggestion that physicians do not document medical visits that are occurring in the post-surgical period to be concerning. As a general matter, Medicare does not require documentation to support a billed service beyond information that the physician would normally maintain in the patient's medical record. Even in the absence of billing Medicare or another insurer, we believe that physicians and other practitioners following standard medical practice would document what occurred during a patient encounter in order to ensure the patient's medical history is accurate and up-to-date, and to facilitate continuity in the patient's medical care.

Comment: One commenter asserted that the 90-day global period was created to prevent two behaviors referred to as "fee-splitting" and "itinerant surgery." According to the commenter, these terms refer to the practice where a surgeon would provide only the surgery and leave postoperative care to other practitioners. The commenter believes these practices are inconsistent with professional standards, and that it is medically necessary and expected by patients that surgeons will evaluate their patients on a daily basis in the hospital and as needed on an outpatient basis during the recovery period.

Response: We do not believe that the global surgical package was designed to ensure or allocate appropriate post-operative care among practitioners. Under Medicare's current global surgery policy, practitioners can agree on the transfer of care during the global period and, in such cases, modifiers are used in order to split the payment between the procedure and the post-operative care. We do not agree that global surgical packages obligate the surgeon to furnish some or all of the post-operative care. Global surgical packages are valued based on the typical service, and we would not expect every surgery to require the same number of follow-up visits. However, we would expect that over a large number of services, the central tendency would reflect the number of visits we included as typical for purposes of valuing the global package; and as discussed above, we have not found that this is necessarily the case. Even if Medicare maintains the 10- and 90-day global surgery packages, there would be no assurance that the surgeon, and not another practitioner, would furnish all or a certain amount of post-operative care (whether by the patient's choice of practitioner or otherwise). The global payment includes payment for post-operative care with the payment for the surgery, which makes it difficult to know whether or by whom the post-operative care was actually furnished unless there is an official transfer of care. We are confident that the surgical community will continue to furnish appropriate care for Medicare beneficiaries irrespective of changes in the structure of payment for surgical services.

Comment: Several commenters stated that if Medicare adopts a policy to pay for post-operative care using E/M codes rather than through a global package, Medicare will likely pay a higher level of E/M visits when they are separately billed than it does currently, as the existing global packages tend to include

more lower level E/M services than those that are generally reported.

Response: We acknowledge that the visits assumed in the global packages are generally valued as lower-level visits than are most commonly furnished, as reflected in Medicare utilization data for separately reportable E/Ms. However, this disparity is only pertinent to the proposal if the global packages are inaccurately valued or, if, under the proposed policy, practitioners who furnish these services are likely to inaccurately report the level of E/M service that is actually being furnished. If the former is true, then we believe this supports the proposal to revalue these services. As with every service, we expect physicians to bill the most appropriate E/M codes that reflect the care that is furnished, including for post-operative care.

Comment: One commenter expressed concern that the proposal to require separate billing for postoperative surgical care provides a basis for the eventual denial of payment to one or more of the postoperative care providers, based on the notion that care furnished by other specialties is duplicative of or replaces care furnished by the surgeon. This commenter stated that multiple providers with differing expertise and training are essential to achieve optimal patient outcomes and expressed concern that this proposal will provide disincentives to optimal patient care.

Response: As we stated in the proposal, we believe that there are various models for postoperative care that can often include multiple providers, and this is another important reason why we believe the services with longer global periods should be transformed to 0-day packages to accommodate heterogeneous models of care that optimize patient outcomes.

Comment: One commenter recommended that CMS establish G-codes for three levels of post-operative visits furnished by the original surgeon or another surgeon with the same board certification, as well as a second set of three level G-codes for postoperative visits furnished by another provider. The commenter also suggested that CMS should develop methods to fairly measure the duration of E/M times through which a large sample of surgeons might report the number and intensity of post-operative visits. The commenter also recommended that CMS track E/M services furnished to surgical patients within the global period by a physician other than the operating surgeon, for the same or similar diagnosis, in order to begin to understand what portion of

postoperative visits are being billed outside of the global period.

The RUC informed CMS that it has identified several large hospital-based physician group practices that internally use CPT code 99024 to report each bundled post-operative visit, and therefore data is already being captured for some Medicare providers. The RUC also suggested that CMS may have denied-claims data available for CPT code 99024 via the Medicare claims processing system. The RUC recommends that CMS work with it to explore the availability, usefulness, and appropriateness of these data from group practices and the CMS denied-claims dataset, in order to gather existing, objective data to validate the actual number of post-operative visits for 10-day and 90-day procedures. The RUC also suggested that CMS should consider reviewing Medicare Part A claims data to determine the length of stay for surgical services furnished in the inpatient acute care hospital setting.

MedPAC stated that data collection could take several years, would be burdensome for CMS and providers, and may be inaccurate since providers would have little incentive to report each visit. Furthermore, MedPAC suggested that such data collection would be unnecessary since the current ratesetting methodology already assumes particular numbers of visits. MedPAC suggested that CMS should reduce the RVUs for the 10- and 90-day global services based on the same assumptions currently used to pay for these services.

Several other commenters agreed with the approach advocated by MedPAC (often referred to as “reverse-building block”) to revaluing the services. These commenters stated that since CMS has increased RVUs for these services proportionate to the number of E/M services assumed to be included in the postoperative period, for the sake of relativity, the RVUs attributed to the visits can be fairly removed in order to value the new 0-day global codes. Many of these commenters acknowledged that this approach would result in negative or other anomalous values for many of these codes, but asserted that codes with anomalous values might then be individually reviewed. MedPAC suggested that if specialty societies or the RUC believe that the new values for specific global codes are inaccurate, they could present evidence that the codes are misvalued to CMS, presumably through the potentially misvalued code public nomination process. MedPAC further states that for codes without accurate post-operative assumptions, CMS could calculate

interim RVUs for these codes based on the average percent reduction for other global codes in the same family.

Many other commenters were against the reverse-building block approach to revaluation. These commenters stated that backing out the bundled E/M services would be highly inappropriate and methodologically unsound since the services were not necessarily valued using a building-block methodology. Many of these commenters, including the RUC, stated that the amount of post-operative work included in the codes can only be appropriately surveyed, vetted, and valued by the RUC.

Response: We appreciate the concerns of commenters regarding the difficulty of revaluing the global surgery codes as 0-day global packages. As we stated in making the proposal, we believe that such stakeholder input and participation in any revaluation will be critical to the accuracy of the resulting values. We will consider all of these comments as we consider mechanisms for revaluations and as we propose new values for specific services. We believe that the challenges involved in revaluation, such as those articulated by commenters, reinforce our understanding that the current construction of the 10- and 90-day global packages are not a sustainable, long-term approach to the accurate valuation of surgical care. As noted above, we will continue to explore appropriate ways of bundling global surgical services.

Comment: In general, commenters supporting the proposal also supported CMS’s proposed timeframe to transition 10-day global codes and 90-day global codes to 0-day global surgical packages by 2017 and 2018, respectively. In contrast, most commenters objecting to, or articulating reservations about, the proposal urged CMS to slow its implementation. Some of these commenters suggested that the process used to establish the current values for these CPT codes is ideal and stated that it would take many years to value the many individual services using the same methodologies.

The RUC stated that there are over 4,200 services within the PFS with a 10-day or 90-day global period, so the scope of the proposal is very large and the transition should be staggered over many years. However, the RUC also pointed out that most of these services have relatively low utilization, as only 268 of them (or 6 percent of 10- or 90-day global surgery services) were performed more than 10,000 times annually based on 2013 Medicare claims data.

Response: We appreciate the concerns of the commenters. We agree with those commenters who urged us to move quickly to value services as accurately as possible. We note that most comments suggesting a delay in revaluation were based on a common underlying view that code-level review of the full set of services by the RUC based on practitioner surveys is the only appropriate way to value the services.

As we stated in making the proposal, we do not believe that surveying practitioners who furnish each of these services is a practical or necessarily advisable approach to appropriate valuation. Regardless of when the proposal is implemented, it seems likely that the number of codes to be revalued is much larger than the number of codes that should or can be surveyed. Through its normal process, the RUC routinely makes annual recommendations regarding several hundred codes, and we acknowledge that thousands of services cannot be valued using the typical RUC process in one year. On the other hand we believe that there are other options for revaluing some of the global surgery codes as 0-day global packages, particularly those of low volume, and we have indicated a willingness to work with the RUC to determine appropriate mechanisms for revaluations. Therefore, although we agree that revaluing such a high number of codes is a significant undertaking, we do not believe that the required revaluations would represent an undue burden between the present and the proposed implementation dates. We also note that in order to focus efforts on revaluing the global surgery packages, we are not asking the RUC to review the nearly 100 services we proposed as potentially misvalued this year under the high expenditure screen. We continue to remain interested in other potential data sources for accurately valuing PFS services, especially the vast majority of 10- and 90-day global codes for which there is not significant volume. We also urge stakeholders to engage with us to help us understand why alternative approaches to the revaluation of the 10- and 90-day global services would require the kind of delay that was urged based on the assumption that the RUC survey approach would be used for all those services.

Additionally, we request stakeholders, including the CPT Editorial Panel and the RUC, to consider the utility of establishing and maintaining separate coding and national Medicare RVUs for the many procedures that have little to no utilization in the Medicare population. For example, there are over 1,000 10-

and 90-day global codes with fewer than 100 annual services in the Medicare database. Although we recognize that some portion of these services may be utilized more extensively by non-Medicare payers, it is also likely that many of these codes may reasonably be consolidated. We request that appropriate coding for surgical services be considered as part of revaluing global surgery.

Comment: Many commenters expressed concerns that requiring beneficiary coinsurance for each follow-up visit could dissuade beneficiaries from returning for necessary follow-up care and, therefore, adversely affect surgical outcomes. Many of these commenters acknowledged that overall patient liability for the total amount of care could be reduced, depending on revaluation, but stated that paying separate coinsurance for follow-up care can cause patients to perceive the net payments as larger, given the frequency of payment required. These commenters stated that the magnitude of these problems might be directly proportionate to how sick the patient is.

Response: We understand the concerns of the commenters, but do not agree that Medicare beneficiaries are unlikely to appreciate the difference between frequency of payment and overall financial liability. We also note that the significant majority of patient encounters with Medicare practitioners generate some degree of beneficiary liability. While liability could prompt the proportion of beneficiaries without secondary insurance to forgo medically reasonable and necessary care for the treatment of illness or injury, we have no reason to conclude that this would be the case specifically for post-operative care. We do acknowledge that surgeons may need to explain the importance of follow-up care so that patients understand and appreciate how compliance with follow-up care can improve the overall quality of care and outcomes. As noted above, while our proposal is to move to 0-day global packages as a simple, immediate adjustment, the agency remains committed to bundling as a key component of payment system delivery reform, and we will consider beneficiary impact as we further consider the appropriate size and construction of a surgical bundle.

Comment: Several commenters expressed concerns that the proposal would result in disjointed or inadequate care and/or disrupt surgical registry data. These commenters suggested that neither patients nor alternate providers are as qualified to determine whether or

not a postoperative visit by the surgeon is necessary.

Response: As discussed above, we do not agree that patients who require the post-operative care of a surgeon are likely to forgo such care if Medicare changes how we pay the surgeon for furnishing that care. Although several commenters expressed these and similar kinds of concerns, none explained how the proposed change in payment would change post operative care. We continue to believe that surgeons will continue to furnish appropriate post operative care to Medicare beneficiaries, and we do not agree that concerns about increased patient liability or disjointed care are warranted.

Comment: Several commenters expressed concerns over other Medicare payment policies related to surgical procedures. Some commenters stated that the current multiple procedure payment reduction policies that apply to all 0-, 10-, and 90-day global codes are only appropriate for 10-day and 90-day globals due to the overlap in resource costs during the post-operative period. Other commenters noted that potential reductions in payment to surgeons to account for the reduced post-operative period would negatively impact practitioners who assist at surgery despite the fact that their professional work and responsibilities have not changed.

Response: We appreciate the issues raised by these commenters. Again, we seek continued input from the stakeholder community regarding these and other issues that need to be considered in order to implement the transition. In the case of the MPPR, we note there are several hundred 0-day global codes where these payment policies currently apply. We are especially interested in understanding why stakeholders do not believe the policies effective for the current 0-day global codes would not similarly be appropriate for the current 10- and 90-day codes that will be revalued as 0-day global codes.

Comment: Many of the commenters who opposed or expressed concern about the proposal urged CMS to consider the extent to which this proposal would increase the administrative burden on CMS, MACs, and providers. Other commenters urged CMS to consider that post-operative visits would be subject to the same documentation requirements and other scrutiny as other separately-reportable PFS services. One commenter representing other payers opposed the proposal due to concerns about predicting the usage of post-operative services.

Response: We considered the administrative burden on both CMS and practitioners who furnish these services in making the proposal. In both cases, we note the administrative burden would be no greater than the burden associated with the vast majority of other services paid through the Medicare PFS. We do not believe that the burden of separately reporting post-operative follow-up visits is particularly or unduly burdensome, given that most office visits paid through the PFS are separately reported under current Medicare policies. In comparison to the number of separately reported visits and other PFS services, the number of visits that likely occur in post-operative periods is relatively small. We do not agree that there are inherent reasons that medically necessary post-operative visits should be exempt from the same documentation and other requirements applicable to other PFS services. We appreciate that changes in Medicare policy may affect other insurers who choose to base their payments on the PFS; however, it is our obligation to set our policies based upon the needs of Medicare and its beneficiaries.

Comment: A few commenters urged CMS to consider the possibility that there could be confusion among practitioners and payers if some payers continue to base payment on the 10- or 90-day post-operative periods.

Response: We believe that payment policies that are appropriate for Medicare may not always be optimal for all payers. However, we seek continued input and analysis from other payers as we engage stakeholders in developing our implementation strategy for the transition of 10- and 90-day global services to 0-day global services.

Comment: Several commenters urged CMS to consult with stakeholders as we develop appropriate plans for the global period transition. These commenters cautioned that the structural reorganization of these services is challenging due to the large set of services that will be impacted and could potentially disrupt well-established payment for certain providers.

Response: We appreciate these recommendations and agree that we should continue to consult with stakeholders regarding the implementation of this proposal.

After consideration of all the comments received regarding this proposal, we are finalizing the proposal to transition and revalue all 10- and 90-day global surgery services with 0-day global periods, beginning with the 10-day global services in CY 2017 and following with the 90-day global services in CY 2018. We note that as we

develop implementation details, including revaluations, we will take into consideration all of the comments we received to our global surgery proposal. We will provide additional details during the CY 2016 rulemaking. We are finalizing a transformation to 0-day global codes because we believe this is the most straightforward way to improve the accuracy of valuation for the various components of global surgical packages, including pre- and post-operative visits and performance of the surgical procedure. However, we remain committed to delivery system reform and ensuring Medicare makes appropriate payment for bundles of services whether our payment covers a period of 0, 10 or 90 days. As we begin revaluation of services as 0-day globals, we will actively assess whether there is a better construction of a bundled payment for surgical services.

We also actively seek the analysis and perspective of all affected stakeholders regarding the best means to revalue these services as 0-day global codes. We urge all stakeholders to engage with us regarding potential means of making the transition as seamless as possible, both for patient care and provider impact. We are considering a wide range of approaches to all details of implementation from revaluation to communication and transition, and we are hopeful that sufficient agreement can be reached among stakeholders on important issues such as revaluation of the global services and appropriate coding for post-operative care. We remain committed to collecting objective data regarding the number of visits typically furnished during post-operative periods and will explore the extant source options presented by commenters as we consider other options as well.

5. Valuing Services That Include Moderate Sedation as an Inherent Part of Furnishing the Procedure

The CPT manual includes more than 300 diagnostic and therapeutic procedures, listed in Appendix G, for which CPT has determined that moderate sedation is an inherent part of furnishing the procedure and, therefore, only the single procedure code is appropriately reported when furnishing the service and the moderate sedation. The work of moderate sedation has been included in the work RVUs for these diagnostic and therapeutic procedures based upon their inclusion in Appendix G. Similarly, the direct PE inputs for these services include those inputs associated with furnishing a typical moderate sedation service. To the extent that moderate sedation is typically

furnished as part of the diagnostic or therapeutic service, the inclusion of moderate sedation in the valuation of the procedure is appropriate.

In the CY 2014 PFS proposed rule (79 FR 40349), we noted that it appeared that practice patterns for endoscopic procedures were changing, with anesthesia increasingly being separately reported for these procedures. For example, one study showed that while the use of a separate anesthesia professional for colonoscopies and upper endoscopies was just 13.5 percent in 2003, the rate more than doubled to 30.2 percent in 2009. An analysis of Medicare claims data showed that a similar pattern is occurring in the Medicare program. We found that, for certain types of procedures such as digestive surgical procedures, a separate anesthesia service is furnished 53 percent of the time. For some of these digestive surgical procedures, the claims analysis showed that this rate was as high as 80 percent.

Our data clearly indicated that moderate sedation was no longer typical for all of the procedures listed in CPT's Appendix G, and, in fact, the data suggested that the percent of cases in which it is used is declining. For many of these procedures in Appendix G, moderate sedation continued to be furnished. The trend away from the use of moderate sedation toward a separately billed anesthesia service was not universal. We found that it differed by the class of procedures, sometimes at the procedure code level, and continued to evolve over time. Due to the changing nature of medical practice in this area, we noted that we were considering establishing a uniform approach to valuation for all Appendix G services for which moderate sedation is no longer inherent, rather than addressing this issue at the procedure level as individual procedures are revalued.

We sought public comment on approaches to address the appropriate valuation of these services. Specifically, we were interested in approaches to valuing Appendix G codes that would allow Medicare to pay accurately for moderate sedation when it is furnished while avoiding potential duplicative payments when separate anesthesia is furnished and billed. To the extent that Appendix G procedure values are adjusted to no longer include moderate sedation, we requested suggestions as to how moderate sedation should be reported and valued, and how to remove from existing valuations the RVUs and inputs related to moderate sedation.

We noted that in the CY 2014 PFS final rule with comment period, we established values for many upper

gastrointestinal procedures, 58 of which were included in Appendix G. For those interim final values, we included the inputs related to moderate sedation. We stated that we did not expect to change existing policies for valuing moderate sedation as inherent in these procedures until we have the opportunity to assess and respond to the comments on the proposed rule on the overall valuation of Appendix G codes.

We received many helpful suggestions in response to our comment solicitation. At this time, we are not making any changes to how we value Appendix G codes for which moderate sedation is an inherent part of the procedure. We intend to address this topic in future notice and comment rulemaking, taking into account the comments we received. In section II.G. of this CY 2015 PFS final rule with comment period, we address interim final values and establish CY 2015 inputs for the lower gastrointestinal procedures, many of which are also listed in Appendix G.

C. Malpractice Relative Value Units (RVUs)

1. Overview

Section 1848(c) of the Act requires that each service paid under the PFS be comprised of three components: Work; PE; and malpractice (MP) expense. As required by section 1848(c) of the Act, beginning in CY 2000, MP RVUs are resource based. Malpractice RVUs for new codes after 1991 were extrapolated from similar existing codes or as a percentage of the corresponding work RVU. Section 1848(c)(2)(B)(i) of the Act also requires that we review, and if necessary adjust, RVUs no less often than every 5 years. For CY 2015, we are proposing to implement the third comprehensive review and update of MP RVUs. For details about prior updates, see the CY 2010 final rule with comment period (74 FR 33537).

2. Methodology for the Proposed Revision of Resource-Based Malpractice RVUs

The proposed MP RVUs were calculated by a CMS contractor based on updated MP premium data obtained from state insurance rate filings. The methodology used in calculating the proposed CY 2015 review and update of resource-based MP RVUs largely paralleled the process used in the CY 2010 update. The calculation required using information on specialty-specific MP premiums linked to a specific service based upon the relative risk factors of the various specialties that furnish a particular service. Because MP premiums vary by state and specialty,

the MP premium information were weighted geographically and by specialty. Accordingly, the proposed MP RVUs were based upon three data sources: CY 2011 and CY 2012 MP premium data; CY 2013 Medicare payment and utilization data; and CY 2015 proposed work RVUs and geographic practice cost indices (GPCIs).

Similar to the previous update, we calculated the proposed MP RVUs using specialty-specific MP premium data because they represent the actual expense incurred by practitioners to obtain MP insurance. We obtained and used MP premium data from state departments of insurance rate filings, primarily for physicians and surgeons. When the state insurance departments did not provide data, we used state rate filing data from the Perr and Knight database, which derives its data from state insurance departments. We used information obtained from MP insurance rate filings with effective dates in 2011 and 2012. These were the most current data available during our data collection process.

We collected MP insurance premium data from all 50 States, the District of Columbia, and Puerto Rico. Rate filings were not available in American Samoa, Guam, or the Virgin Islands. Premiums were for \$1 million/\$3 million, mature, claims-made policies (policies covering claims made, rather than those covering services furnished, during the policy term). A \$1 million/\$3 million liability limit policy means that the most that would be paid on any claim is \$1 million and the most that the policy would pay for claims over the timeframe of the policy is \$3 million. We made adjustments to the premium data to reflect mandatory surcharges for patient compensation funds (funds to pay for any claim beyond the statutory amount, thereby limiting an individual physician's liability in cases of a large suit) in states where participation in such funds is mandatory. We attempted to collect premium data representing at least 50 percent of the medical MP premiums paid.

We included premium information for all physician and NPP specialties, and all risk classifications available in the collected rate filings. Most insurance companies provided crosswalks from insurance service office (ISO) codes to named specialties. We matched these crosswalks to Medicare primary specialty designations (specialty codes). We also used information we obtained regarding surgical and nonsurgical classes. Some companies provided additional surgical subclasses; for example, distinguishing family practice

physicians who furnish obstetric services from those who do not.

Although we collected premium data from all states and the District of Columbia, not all specialties had premium data in the rate filings from all states. Additionally, for some specialties, MP premiums were not available from the rate filings in any state. Therefore, for specialties for which there was not premium data for at least 35 states, and specialties for which there was not distinct premium data in the rate filings, we crosswalked the specialty to a similar specialty, conceptually or by available premium data, for which we did have sufficient and reliable data. Additionally, we crosswalked three specialties—physician assistant, registered dietitian and optometry—for which we had data from at least 35 states to a similar specialty type because the available data contained such extreme variations in premium amounts that we found it to be unreliable. The range in premium amounts for registered dietitians is \$85 to \$20,813 (24,259 percent), for physician assistants is \$614 to \$35,404 (5,665 percent), and for optometry is \$189 to \$10,798 (5,614 percent). We crosswalked these specialties to allergy and immunology, the specialty with the lowest premiums for which we had sufficient and reliable data.

Our proposed methodology for updating the MP RVUs conceptually followed the specialty-weighted approach, used in the CY 2010 update. The specialty-weighted approach bases the MP RVUs for a given service upon a weighted average of the risk factors of all specialties furnishing the service. This approach ensures that all specialties furnishing a given service are accounted for in the calculation of the MP RVUs. We also continued to use the risk factor of the dominant specialty for rarely billed services (that is, when CY 2013 claims data reflected allowed services of less than 100).

We proposed minor refinements for updating the CY 2015 MP RVUs as compared to the previous update. These refinements included calculating a combined national average surgical premium and risk factor for neurosurgery and neurology and updating the list of invasive cardiology service HCPCS codes (for example, cardiac catheterization and angioplasty) to be classified as surgery for purposes of assigning service level risk factors. Additionally, we proposed to classify injection procedures used in conjunction with cardiac catheterization as surgery (for purposes of assigning a service specific risk factor). To calculate the risk factor for TC services we

proposed to use the *mean* umbrella non-physician MP premiums obtained from Radiology Business Management Association (RBMA) survey data, used for the previous MP RVU update in 2010, and adjusted the premium data to reflect the change in non-surgical premiums for all specialties since the previous MP RVU update.

As discussed in the CY 2015 proposed rule (79 FR 40354 through 40355), we did not include an adjustment under the anesthesia fee schedule to reflect updated MP premium information and stated that we intend to propose an anesthesia adjustment for MP in the CY 2016 PFS proposed rule. We also requested comments on how to reflect updated MP premium amounts under the anesthesiology fee schedule.

We posted our contractors report, "Report on the CY 2105 Update of Malpractice RVUs" on the CMS Web site. The report on MP RVUs for the CY 2015 proposed rule and the proposed MP premium amounts and specialty risk factors are accessible from the CMS Web site under the supporting documents section of the CY 2015 PFS proposed rule at <http://www.cms.gov/PhysicianFeeSched/>. A more detailed explanation of our proposed MP RVU update can be found in the CY 2015 PFS proposed rule (79 FR 40349 through 40355).

3. Response to Public Comments

We received over 70 industry comments on the CY 2015 proposed MP RVU update. A summary of the comments we received on the proposed MP RVU update and our responses are discussed below.

Comment: Two commenters supported our proposal to combine the surgical premium data for neurosurgery and neurology for establishing the surgical risk factor for neurosurgery.

Response: We agree with the commenters and will finalize our approach for determining the surgical premium for neurosurgery as proposed. We will combine surgical premiums for neurology and neurosurgery to calculate a national average surgical premium and risk factor for neurosurgery.

Comment: Three commenters requested that we phase in the reduction for ophthalmology and optometry services over 2 years. The commenters stated that the reduction is due in part to an error we made in calculating the MP RVUs for ophthalmology and optometry codes under the previous MP RVU update in CY 2010. The commenters stated that an immediate implementation of the correction would result in significant

payment reductions for ophthalmologists.

Response: We note that for the CY 2015 MP RVU update we did not correct the mistake that was made in CY 2010. For the CY 2015 MP update we recalculated the MP RVUs based upon the most recently available data for all services, including ophthalmic services. Accordingly, the proposed MP RVU update reflects the use of updated MP premium data and risk factors by specialty and is not affected in any way by the CY 2010 MP RVUs. In doing so, even though the proposed CY 2015 ophthalmology non-surgical risk factor was 14 percent greater than the CY 2010 non-surgical risk factor and the proposed surgical risk factor was 17 percent greater, the proposed MP RVUs for most services with significant ophthalmology volume decreased because the CY 2010 error resulted in MP RVUs that were higher than they should have been. That is, the reduction in MP RVUs for ophthalmology and optometry are solely due to overpayments made due to a mistake during the previous MP RVU update rather than a proposed change in methodology or the use of updated premium data. We do not believe that a previous error is sufficient justification for not fully implementing updated MP RVUs based on more recent premium data. Therefore, we will implement the updated MP RVUs for ophthalmology and optometry services as proposed.

Comment: We received comments regarding the application of our specialty weighted approach for calculating service level risk factors for surgical services. For instance, the same commenters that requested a 2-year phase in of the reduction to ophthalmology services also requested that we exclude optometry from calculating the risk factor for ophthalmic surgery. One commenter stated that "MP RVUs for cataract and other ophthalmic surgeries are deflated because CMS assumes that optometry is providing the surgical portion of the procedure." The commenter also stated that optometrists are involved only during the pre- or post-procedure periods of ophthalmic surgery. Another specialty society stated that it appears that CMS's methodology for calculating service level risk factors for surgical services "may include the allowed services for surgical assistance possibly discounted to reflect the assistant role under payment policy." The commenter also stated that "specialties that assist at the procedure do not perform it, and the assistant's associated MP risk factor has no bearing on the MP cost for the surgeon."

Response: The commenter is correct to say that we calculated service level risk factors based on the mix of all practitioners billing for a given service and that the specialty weighted approach is applied to both surgical and non-surgical services. That is, we apply the risk factor(s) of all specialties involved with furnishing the surgical procedure to calculate service level risk factors and MP RVUs. For assistants at surgery, we discount the utilization to reflect his or her role in furnishing the surgical procedure. Although we agree that MP cost for the surgeon may not be affected by the surgical assistant's MP cost, we do not agree with the suggestion that assistants at surgery should be excluded from our specialty weighted approach for determining service level MP risk factors and MP RVUs for surgical services. We believe it is appropriate to apply the specialty risk factor(s) of all practitioners participating in and receiving a payment for the surgical procedure for purposes of determining a service level risk factor and thus the payment for that service. If we were to exclude the risk factors of some specialties that bill a specific code from the calculation of the service level risk factor, the resulting MP RVU would not reflect all utilization. Similarly, we also disagree with the suggestion that pre- and post- utilization should be removed from determining MP RVUs for ophthalmic surgical services. The resources associated with pre- and post-operative periods for ophthalmic surgery are included in the total RVUs for the global surgical package. Accordingly, if we did not include the portion of utilization attributed to pre- and post-operative visits in the calculation of service level risk factors, the MP RVUs for global surgery would overstate the MP costs.

We note that in both of these cases by using the discounted utilization file the weighted average that we use reflects only the proportion of the utilization by these practitioners and only at the payment rate made. Including specialty utilization for all practitioners involved in furnishing the global service reflects the MP risk for the entire global service.

Comment: We received two comments regarding how risk factors are assigned to existing services without Medicare utilization. The commenters stated that we crosswalk to the risk factor of an analogous source code with Medicare utilization for new codes but assign the average risk factor for all physicians to existing services without Medicare utilization. The commenters contend that "it is inappropriate for a service to have fluctuating MP risk factors simply due to whether it is reported in

Medicare claims data for a given year." The commenters requested that we crosswalk existing services without Medicare utilization to a recommended source code.

Response: We used the most recently available Medicare claims data (that is, from CY 2013) to determine the service level risk factors, either based on the risk factors of the actual mix of practitioners furnishing the service, or in the case of low volume services, the risk factor of the dominant specialty. We disagree with the commenters' suggestion to assign the risk factor of a recommended specialty to an existing service without Medicare utilization as indicated by our most recently available claims data. In the absence of Medicare utilization we continue to believe that the most appropriate risk factor is the weighted average risk factor for all service codes. The proposed weighted average risk factor for all service codes was 2.11. Using the weighted average risk factor for all services effectively neutralizes the impact of updated MP premiums and risk factors for any specific specialty (or mix of specialties).

Comment: The AMA and the RUC and other commenters agreed with the majority of our proposed claims based dominant specialty designations for codes with less than 100 allowed services; however, the commenters disagreed with our proposed dominant specialty for some services. The commenters believe that some claims have been miscoded, resulting in erroneous specialty designations. One commenter stated that using the dominant specialty from the claims data resulted in unjustifiably low MP RVUs for congenital heart surgery. The commenter stated that congenital heart surgery can only be done by a heart surgeon and requested that we override the dominant specialty in our claims data and use the RUCs recommended specialty.

Response: As discussed in the previous response, we proposed to use CY 2013 claims data to determine the service level MP risk factors, either based on the mix of practitioners furnishing the service, or in the case of low volume services, assigning the risk factor of the dominant specialty. We continue to believe that use of actual claims data to determine the dominant specialty is preferable to using a "recommended" specialty. However, we recognize that anomalies in the claims data can occur that would affect the dominant specialty for low volume services, and therefore resulting in the need for a subjective review of some services in place of a complete reliance on claims data. To that end, we

reviewed the commenter's recommendations for overriding the dominant specialty from our claims data with a recommended specialty. After careful consideration of the comments, we will override the dominant specialty from Medicare claims data when the dominant specialty from our claims data

is inconsistent with a specialty that could be reasonably expected to furnish the service. For example, our claims data indicates that pulmonary disease is the dominant specialty for HCPCS code 33622 (Reconstruction of complex cardiac anomaly), however as the commenter mentioned, this service is

furnished by heart surgeons. A complete listing of low volume services for which we will override the claims based dominant specialty with the recommended specialty to assign a service level risk factor is illustrated in Table 12.

TABLE 12—LOW VOLUME SERVICE CODES WHERE ASSIGNED SPECIALTY USED RATHER THAN CLAIMS BASED DOMINANT SPECIALTY

HCPCS Code	Short descriptor	Claims based dominant specialty	Assigned specialty
25490	Reinforce radius	Otolaryngology	Orthopedic Surgery.
26556	Toe joint transfer	Pulmonary Disease	Orthopedic Surgery.
31320	Diagnostic incision larynx	Cardiology	Otolaryngology.
33620	Apply r&l pulm art bands	Anesthesiology	Cardiac Surgery.
33621	Transthor cath for stent	Cardiology	Cardiac Surgery.
33622	Redo compl cardiac anomaly	Pulmonary Disease	Cardiac Surgery.
33697	Repair of heart defects	Cardiology	Cardiac Surgery.
33766	Major vessel shunt	General Surgery	Cardiac Surgery.
36261	Revision of infusion pump	General Practice	General Surgery.
43341	Fuse esophagus & intestine	Gastroenterology	Thoracic Surgery.
43350	Surgical opening esophagus	General Practice	General Surgery.
49491	Rpr hern preemie reduc	General Practice	General Surgery.
50686	Measure ureter pressure	Internal Medicine	Urology.
54352	Reconstruct urethra/penis	Pediatric Medicine	Urology.
54380	Repair penis	Gastroenterology	Urology.
61000	Remove cranial cavity fluid	Family Practice	Neurosurgery.
61558	Excision of skull/sutures	Family Practice	Neurosurgery.
61567	Incision of brain tissue	Cardiology	Neurosurgery.
74710	X-ray measurement of pelvis	Thoracic Surgery	Diagnostic Radiology.
96003	Dynamic fine wire emg	Cardiology	Physical Therapist/Independent Practice.
96420	Chemo ia push technique	Urology	Hematology Oncology.
99170	Anogenital exam child w imag	Ophthalmology	Pediatric Medicine.
99461	Init nb em per day non-fac	Cardiac Electrophysiology	Pediatric Medicine.

Comment: Some commenters requested that we crosswalk gynecological oncology to general surgery, instead of crosswalking to obstetrics/gynecology because gynecological oncology is more akin to general surgery procedures than obstetrics/gynecology. One specialty society stated that gynecological oncologists are predominantly cancer surgeons with MP risk similar to general surgery.

Response: We agree with the commenters and will crosswalk gynecological oncology to the general surgery premium data and risk factor.

Comment: One commenter requested that we crosswalk clinical laboratory to pathology instead of the risk factor used for TC services because clinical laboratories and pathologists render essentially identical medical procedures that are paid on the Medicare PFS.

Response: We believe that the MP risk for clinical laboratories is more akin to the MP risk of radiation therapy centers, mammography screening centers and IDTFs, for which we assigned the TC risk factor, than to the MP risks for pathologists. The commenters did not provide sufficient rationale to support

that MP risk for clinical laboratories is similar to the MP risk of pathologists. Therefore, we will crosswalk clinical laboratory to the TC risk factor as proposed.

Comment: One commenter encouraged us to crosswalk the interventional pain management specialty to a specialty that more closely reflects the risks and services associated with interventional pain management, such as interventional radiology or a comparable surgical subspecialty.

Response: We believe that the MP risk associated with interventional pain management is conceptually similar to the MP risk for anesthesiology more so than to the MP risk for interventional radiology. Given that the commenters did not provide sufficient rationale to support that MP risk for interventional pain management is similar to interventional radiology or to a comparable surgical specialty, we will crosswalk interventional pain management to anesthesiology as proposed.

Comment: We received contrasting comments on our proposal to crosswalk NPPs to the premium and risk factor calculated for allergy/immunology. For

instance, one commenter acknowledged the difficulty in identifying comprehensive, accurate premium data across the majority of states, especially for NPPs. To that end, the commenter supported our decision to crosswalk the MP premiums of NPPs to the lowest physician risk factor, allergy/immunology. Another commenter, specifically supported crosswalking registered dietitians to the risk factor calculated for allergy/immunology.

In contrast, the AMA and other commenters did not support crosswalking NPPs with insufficient or unreliable premium data to the premium amounts and risk factor used for allergy/immunology. The commenters stated that allergy/immunology premiums overstate NPP premiums and requested that we use the generally lower MP survey data from the Physician Practice Information Survey (PPIS) for NPPs instead of crosswalking NPPs to the lowest physician specialty (allergy/immunology) or use some other measure of central tendency within the existing collected premium data to determine accurate MP premium risk factors for NPPs. Another commenter suggested that we work with the AMA

to obtain the necessary data to ensure the process for reviewing and updating MP rates is accurate for all providers.

Response: As discussed previously in this section, the resource-based MP RVUs are based on verifiable MP premium data. We do not believe it would be appropriate to base the MP RVUs for nonphysician specialties on survey data and use premium data for all other specialties. Therefore, we do not agree with the commenters that suggested using survey data for NPPs and will finalize the specialty crosswalks for NPPs as proposed. However, in light of the commenter's suggestions, we will explore ways to enhance our MP premium data collection efforts to obtain better premium data for NPPs for future updates. We will also explore other potential measures of central tendency for determining the "indexed" specialty as an alternative to using the premium values of the lowest specialty.

Comment: We received two comments regarding the data and or methodology used to calculate the TC and PC of diagnostic services. One specialty group noted that the proposed MP RVUs for the TC of some diagnostic services increased while the MP RVUs for the PC decreased. Specifically, the commenter questioned why the MP RVUs for the PC of diagnostic cardiac catheterization as described by HCPCS codes 93451 through 93461 decreased by 6 to 12 percent while the TC portion for these codes increased by 20 to 33 percent. The commenter encouraged us to review the reasons for this shift to TC MP RVUs. Additionally, the RBMA submitted updated MP premium information collected from IDTFs in 2014. The RBMA requested that we use the recently obtained data reflecting the median "50th percentile" premium data for "umbrella non-physician MP liability" for calculating CY 2015 MP RVUs for TC services.

Response: To calculate the risk factor for TC services we used the *mean* umbrella non-physician MP premiums obtained from the RBMA survey data (used for the previous MP RVU update in 2010) and adjusted the data to reflect the change in non-surgical premiums for all specialties since the previous MP RVU update, for example, \$9,374 deflated by -20.41 percent = \$7,455. However, given that the premiums of the lowest physician specialty (allergy/immunology) decreased by more than 20 percent, the proposed CY 2015 risk factor for TC services increased from the previous update in CY 2010 from 0.86 to 0.91, resulting in minor increases in MP RVUs for TC services. However, given that the MP RVUs for TC services

are generally low, any increase to the MP RVUs could result in a significant percentage increase. For example, the proposed CY 2015 MP RVU for HCPCS code 93455 increased from 0.04 to 0.05 yielding a 25 percent increase. Therefore, a minor increase in MP RVUs for a TC service could result in a significant percentage change.

We believe that using the updated RBMA premium data without further study is problematic because the updated data reflects only the *median* umbrella non-physician MP premium, rather than the mean as was used for the 2010 MP RVU update and the proposed 2015 MP RVU update.

We believe further study is necessary to reconcile comments on the use of updated RBMA premium data for TC services (which would result in an increase MP RVU for TC services) and our current methodology for calculating the risk factor for PC services relative to the global service and TC service. Therefore, we will finalize the TC premium data as proposed and maintain our current methodology for calculating the PC risk factor. We will consider the request to use the updated premium information from RBMA and alternatives to our current methodology for calculating the PC risk factor as part of our further study and would propose any changes through future rulemaking.

Comment: Several commenters supported our proposal to classify cardiac catheterization and angioplasty services as surgical procedures for the purpose of establishing service level risk factors. The commenters also agreed with our proposal to apply the surgical risk factor to injection procedures used in conjunction with cardiac catheterization. The same commenters identified additional cardiac catheterization and angioplasty services that were not included on the proposed list of invasive cardiology services. Specifically, the commenters requested that we consider adding HCPCS codes 92961, 92986, 92987, 92990, 92992, 92993, 92997, and 92998 to the list of invasive cardiology procedures classified as surgery for purposes of assigning service level risk factors because the MP risk for these services is similar to surgery.

Response: We agree that the MP risk associated with the cardiac catheterization and angioplasty services mentioned by the commenters are more akin to surgical procedures than most non-surgical services. Therefore, we will add cardiac catheterization and angioplasty services as described by HCPCS codes 92961, 92986, 92987, 92990, 92997, and 92998 to the list of services outside of the surgical HCPCS

code range to be considered surgery for purposes of assigning service level MP risk factors. We note that HCPCS codes 92992 and 92993 are contractor-priced codes, wherein the Medicare claims processing contractors establish RVUs and payment amounts for these services. Therefore, we are not adding HCPCS codes 92992 and 92993.

Comment: One commenter stated that several injection codes were not included in the list of services outside of the surgical HCPCS code range considered surgery. The commenter requested that we add injection services as described by HCPCS codes 93565, 93566, 93567, and 93568 to the services considered as surgery.

Response: The commenter is mistaken. As discussed in the CY 2015 proposed rule (79 FR 40353 through 40354), we included the injection procedure codes mentioned by the commenter on the list of services outside of the surgical HCPCS code range to be considered surgery for purposes of assigning service level MP risk factors.

Comment: One commenter questioned why the MP RVUs decrease for cardiac catheterization services as described by HCPCS codes 93530, 93531 and 93580. The commenter stated that our proposal to assign the surgical risk factor to invasive cardiology services outside of the surgical HCPCS code range should result in an increase in MP RVUs.

Response: Cardiac catheterizations as described by HCPCS codes 93530, 93531 and 93580 are currently on the list of invasive cardiology services classified as surgery for purposes of assigning service level risk factors. Therefore, the MP RVUs for HCPCS codes 93530, 93531, 93580 were calculated in the last update using the surgical risk factor applicable to the specialty(s) furnishing these services. As discussed previously in this section, the service level risk factors reflect the average risk factor (weighted by allowed services) of the specialties furnishing a given service. Changes in the specialty mix since the previous MP RVU update in 2010 resulted in a decrease in MP RVUs for HCPCS codes 93530, 93531, and 93580. That is, the percentage of allowed services attributed to cardiology decreased for these service codes while the percentage of allowed services furnished by other specialties with risk factors lower than cardiology, such as internal medicine and pediatric medicine, increased.

Comment: Many commenters requested an explanation as to why the MP RVUs decreased for 4 out of the 6 newly bundled image guided breast biopsy procedures. The commenters

stated that given that the MP RVUs assigned to breast biopsy codes are being reduced, CMS is not appropriately capturing the risk a physician assumes when performing a procedure to diagnose cancer. Several commenters also explained that the misdiagnosis of breast cancer is a leading source of MP litigation and that reduction in payment for breast biopsies will have an impact on patient care.

Response: For the image guided breast biopsy procedures as described by HCPCS codes 19081 through 19086, we used the risk factors from source codes as recommended by the RUC. The source codes for breast biopsy codes 19081, 19082, 19083, 19084, 19085 and 19086 are HCPCS codes 32553, 64480, 32551, 64480, 36565, and 76812, respectively. Given that the proposed risk factors for HCPCS codes 32553, 64480, and 32551 decreased from 2014 to 2015, the corresponding “destination” service codes, that is HCPCS codes 19081, 19082, 19083, and 19084 also decreased.

Comment: Several commenters recommended that we implement an annual collection and review of MP premium data and rescale the MP RVUs each year, as we do with the PE RVUs. The commenters also stated that an annual update would provide additional transparency and allow stakeholders to identify potential problems and or improvements to MP RVUs more frequently.

Response: We appreciate the comments from stakeholders regarding the frequency that we currently review changes in MP premium data. As discussed in the CY 2015 PFS proposed rule (79 FR 40349 through 40355), there are two main aspects to the update of MP RVUs, recalculation of specialty risk factors based upon updated premium data and recalculation of service level RVUs based upon the mix of practitioners providing the service. We will consider the recommendation from stakeholders to conduct annual MP RVU updates to reflect corrections and changes in the mix of practitioners providing services. We will also consider the appropriate frequency for collecting new MP premium data. After reviewing these issues, we would address potential changes regarding the frequency of MP RVU updates in a future proposed rule.

Comment: One commenter urged us to calculate risk factors for all specialties approved by the American Board Medical Specialties (ABMS) since 2010. The commenter stated that by using the approved ABMS specialties, all specialties and subspecialties will be represented, including the recently

approved sub-specialty of Female Pelvic Medicine and Reconstructive Surgery.

Response: We calculate service level risk factors based on the mix of specialties that furnish a given service as indicated by our claims data. Medicare claims data reflects the service volume by Medicare primary specialty designations. Therefore, we can only use MP risk factors by Medicare primary specialty codes.

Comment: We received two comments regarding our discussion of how to reflect updated MP premium data under the anesthesiology fee schedule. One commenter supported our decision to delay the anesthesia MP update and requested to work with us on developing an appropriate method for updating the MP component associated with anesthesia fee schedule services. Another commenter suggested using mean anesthesia MP premiums per provider over a 4- or 5-year period prorated by Medicare utilization to yield the MP expense for anesthesia services. The commenter stated that the calculation of premiums over a longer period of time renders the average more accurate and less volatile than a calculation over a 1-year period.

Response: We appreciate the comments on our potential approach for updating the MP resource costs for anesthesia fee schedule services. We will consider the commenter's suggestions to use multi-year average premiums as we develop a method for updating MP payments for services paid on the anesthesia fee schedule.

4. Result of Evaluation of Comments

After consideration of the public comments received on the CY 2015 MP RVU update, we are finalizing the CY 2015 MP RVU update as proposed with minor modifications. We are crosswalking gynecological oncology to the risk factor for general surgery (instead of the risk factor for obstetrics gynecology). We are also adding HCPCS codes 92961, 92986, 92987, 92990, 92997, and 92998 to the list of services outside of the surgical HCPCS code range considered as surgery for purposes of assigning service level risk factors. Additionally, for determining the risk factor for low volume services, we are overriding the dominant specialty from our claims data with the recommended specialty for the low volume service codes listed in Table 12. For all other low volume services, we are finalizing our proposal to use the risk factor of the dominant specialty from our Medicare claims data. The MP premium amounts, specialty risk factors, and a complete list of service codes outside the surgical HCPCS code

range considered surgery for the purpose of assigning service level risk factors, may be found on the CMS Web site under the supporting documents section of the CY 2015 PFS final rule with comment period.

Additional information on the CY 2015 update may be found in our contractor's report, “Final Report on the CY 2105 Update of Malpractice RVUs,” which is available on the CMS Web site. It is also located under the supporting documents section of the CY 2015 PFS final rule with comment period located at <http://www.cms.gov/PhysicianFeeSched/>.

D. Geographic Practice Cost Indices (GPCIs)

1. Background

Section 1848(e)(1)(A) of the Act requires us to develop separate Geographic Practice Cost Indices (GPCIs) to measure relative cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, PE, and MP). Although the statute requires that the PE and MP GPCIs reflect the full relative cost differences, section 1848(e)(1)(A)(iii) of the Act requires that the work GPCIs reflect only one-quarter of the relative cost differences compared to the national average. In addition, section 1848(e)(1)(G) of the Act sets a permanent 1.5 work GPCI floor for services furnished in Alaska beginning January 1, 2009, and section 1848(e)(1)(I) of the Act sets a permanent 1.0 PE GPCI floor for services furnished in frontier states (as defined in section 1848(e)(1)(I) of the Act) beginning January 1, 2011. Additionally, section 1848(e)(1)(E) of the Act provided for a 1.0 floor for the work GPCIs, which was set to expire on March 31, 2014. However, section 102 of the PAMA extended application of the 1.0 floor to the work GPCI through March 31, 2015.

Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPCIs at least every 3 years. Section 1848(e)(1)(C) of the Act requires that “if more than 1 year has elapsed since the date of the last previous adjustment, the adjustment to be applied in the first year of the next adjustment shall be 1/2 of the adjustment that otherwise would be made.” We completed a review and finalized updated GPCIs in the CY 2014 PFS final rule with comment period (78 FR 74390). Since the last GPCI update had been implemented over 2 years prior, CY 2011 and CY 2012, we phased in 1/2 of the latest GPCI adjustment in CY 2014. We also revised the cost share

weights that correspond to all three GPCIs in the CY 2014 PFS final rule with comment period. We calculated a corresponding geographic adjustment factor (GAF) for each PFS locality. The GAFs are a weighted composite of each area's work, PE and MP GPCIs using the national GPCI cost share weights. Although the GAFs are not used in computing the fee schedule payment for a specific service, we provide them because they are useful in comparing overall areas costs and payments. The actual effect on payment for any actual service will deviate from the GAF to the extent that the proportions of work, PE and MP RVUs for the service differ from those of the GAF.

As previously noted, section 102 of the PAMA extended the 1.0 work GPCI floor through March 31, 2015. Therefore, the CY 2015 work GPCIs and summarized GAFs were revised to reflect the 1.0 work floor. Additionally, as required by sections 1848(e)(1)(G) and 1848(e)(1)(I) of the Act, the 1.5 work GPCI floor for Alaska and the 1.0 PE GPCI floor for frontier states are permanent, and therefore, applicable in CY 2015.

Comment: A few commenters requested that we extend the 1.0 work GPCI floor beyond March 31, 2015.

Response: As discussed in section II.D.1, the 1.0 work GPCI floor is established by statute and expires on March 31, 2015. We do not have authority to extend the 1.0 work GPCI floor beyond March 31, 2015.

As discussed in the CY 2014 PFS final rule with comment period (78 FR 74380) the updated GPCIs were calculated by a contractor to CMS. We used updated Bureau of Labor and Statistics Occupational Employment Statistics (BLS OES) data (2009 through 2011) as a replacement for 2006 through 2008 data for purposes of calculating the work GPCI and the employee compensation component and purchased services component of the PE GPCI. We also used updated U.S. Census Bureau American Community Survey (ACS) data (2008 through 2010) as a replacement for 2006 through 2008 data for calculating the office rent component of the PE GPCI. To calculate the MP GPCI we used updated malpractice premium data (2011 and 2012) from state departments of insurance as a replacement for 2006 through 2007 premium data. We also noted that we do not adjust the medical equipment, supplies and other miscellaneous expenses component of the PE GPCI because we continue to believe there is a national market for these items such that there is not a significant geographic variation in

relative costs. Additionally, we updated the GPCI cost share weights consistent with the modifications made to the 2006-based MEI cost share weights in the CY 2014 final rule with comment period. As discussed in the CY 2014 final rule with comment period, use of the revised GPCI cost share weights changed the weighting of the subcomponents within the PE GPCI (employee wages, office rent, purchased services, and medical equipment and supplies). For a detailed explanation of how the GPCI update was developed, see the CY 2014 final rule with comment period (78 FR 74380 through 74391).

2. Proposed Changes to the GPCI Values for the Virgin Islands Payment Locality

As discussed in the CY 2015 proposed rule (79 FR 40355 through 40356) the current methodology for calculating locality level GPCIs relies on the acquisition of county level data (when available). Where data for a specific county are not available, we assign the data from a similar county within the same payment locality. The Virgin Islands have county level equivalents identified as districts. Specifically, the Virgin Islands are divided into 3 districts: Saint Croix; Saint Thomas; and Saint John. These districts are, in turn, subdivided into 20 sub-districts. Although the Virgin Islands are divided into these county equivalents, county level data for the Virgin Islands are not represented in the BLS OES wage data. Additionally, the ACS, which is used to calculate the rent component of the PE GPCI, is not conducted in the Virgin Islands, and we have not been able to obtain malpractice insurance premium data for the Virgin Islands payment locality. Given the absence of county level wage and rent data and the insufficient malpractice premium data by specialty type, we have historically set the three GPCI values for the Virgin Islands payment locality at 1.0.

For CY 2015, we explored using the available data from the Virgin Islands to more accurately reflect the geographic cost differences for the Virgin Islands payment locality as compared to other PFS localities. Although county level data for the Virgin Islands are not represented in the BLS OES wage data, aggregate territory level BLS OES wage data are available. We believe that using aggregate territory level data is a better reflection of the relative cost differences of operating a medical practice in the Virgin Islands payment locality as compared to other PFS localities than the current approach of assigning a value of 1.0. At our request, our contractor calculated the work GPCI,

and the employee wage component and purchased services component of the PE GPCI, for the Virgin Islands payment locality using aggregated 2009 through 2011 BLS OES data.

As discussed in this section, the ACS is not conducted in the Virgin Islands and we have not been able to obtain malpractice premium data for the Virgin Islands payment locality. Therefore, we assigned a value of 1.0 for the rent index of the PE GPCI and to the MP GPCI.

Using aggregate territory-level BLS OES wage data resulted in a -2.3 percent decrease in the work GPCI, a -4.48 percent decrease in the PE GPCI and a -3.2 percent decrease to the GAF for the Virgin Islands payment locality. However, with the application of the 1.0 work GPCI floor, there is no change to the work GPCI and the overall impact of using actual BLS OES wage data on the Virgin Islands payment locality is only reflected by the change in PE GPCI (-4.48 percent) resulting in a -2.00 percent decrease to the GAF. As mentioned previously in this section, since we have not been able to obtain malpractice premium data for the Virgin Islands payment locality we maintained the MP GPCI at 1.0. As such, we did not propose any changes to the MP GPCI.

We requested comments on our proposal to use aggregate territory-level BLS OES wage data to calculate the work GPCI and the employee wage component and purchased services component of the PE GPCI for the Virgin Islands payment locality beginning for CY 2015, and for future GPCI updates. However, we did not receive any specific comments on this proposal. As discussed above, we believe that using aggregate territory level BLS OES wage data is a better reflection of the relative cost differences of operating a medical practice in the Virgin Islands payment locality as compared to other PFS localities than the current approach of assigning a value of 1.0. Therefore, we will finalize the changes to the GPCI values for the Virgin Islands payment locality as proposed. See Addenda D and E for the CY 2015 GPCIs and summarized GAFs. Additional information on the changes to GPCI values for the Virgin Islands payment locality may be found in our contractor's report, "Revised Final Report on the CY 2014 Update of the Geographic Practice Cost Index for the Medicare Physician Fee Schedule," which is available on the CMS Web site. It is located under the supporting documents section of the CY 2015 PFS final rule with comment period located at <http://www.cms.gov/PhysicianFeeSched/>.

3. Additional Comments

We received several comments on topics that are not within the scope of proposals in the CY 2015 PFS proposed rule. These comments are briefly discussed below.

Comment: Many commenters continued to request an increase in the GPCI values for the Puerto Rico payment locality. The commenters stated that the cost of practicing medicine in Puerto Rico continues to rise. The commenters believe that commercial rent and utility costs, and the cost of obtaining medical equipment and supplies are higher in Puerto Rico than many states and territories. Commenters contend that the data used to calculate GPICs do not accurately reflect the cost of operating a medical practice in Puerto Rico.

Response: Aside from proposing to use territory-wide wage data for the Virgin Islands payment locality, we finalized the methodology and values for the 7th GPCI update in the CY 2014 PFS final rule with comment period. We did not propose any changes to the GPICs for the Puerto Rico payment locality, and the commenters on the CY 2015 PFS proposed rule raised the same issues they raised in response to the proposed GPCI update that we finalized in CY 2014. In the CY 2014 PFS final rule with comment period (78 FR 74380 through 74391), we summarized these comments and responded to these issues.

Comment: A few commenters stated that GPICs for rural areas are too low which leads to reduced numbers of rural practitioners and reduced access to care. Two commenters stated that the PE GPCI does not account for differences in practice costs for x-rays and imaging studies. The same commenters and another commenter also requested that we replace the current method for calculating the work GPICs with one that reflects the labor market for physicians and other health professionals as recommended by MedPAC. Another commenter raised questions about state patient compensation fund surcharges for malpractice insurance and the implications of those for the MP GPCI values. Additionally, we received a comment about the physician fee schedule payment localities.

Response: As noted in this section, we finalized the 7th GPCI update in the CY 2014 PFS final rule with comment period and, other than the proposal relating to the use of territory-wide wage data for the Virgin Islands payment locality, we did not propose any further changes in the CY 2015 PFS proposed

rule. We will consider these points raised by commenters when we develop a proposal for the 8th GPCI update.

E. Medicare Telehealth Services

1. Billing and Payment for Telehealth Services

Several conditions must be met in order for Medicare payments to be made for telehealth services under the PFS. Specifically, the service must be on the list of Medicare telehealth services and meet all of the following additional requirements for coverage:

- The service must be furnished via an interactive telecommunications system.
- The practitioner furnishing the service must meet the telehealth requirements, as well as the usual Medicare requirements.
- The service must be furnished to an eligible telehealth individual.
- The individual receiving the services must be in an eligible originating site.

When all of these conditions are met, Medicare pays an originating site fee to the originating site and provides separate payment to the distant site practitioner furnishing the service.

Section 1834(m)(4)(F)(i) of the Act defines Medicare telehealth services to include consultations, office visits, office psychiatry services, and any additional service specified by the Secretary, when furnished via a telecommunications system. We first implemented this statutory provision, which was effective October 1, 2001, in the CY 2002 PFS final rule with comment period (66 FR 55246). We established a process for annual updates to the list of Medicare telehealth services as required by section 1834(m)(4)(F)(ii) of the Act in the CY 2003 PFS final rule with comment period (67 FR 79988).

As specified at § 410.78(b), we generally require that a telehealth service be furnished via an interactive telecommunications system. Under § 410.78(a)(3), an interactive telecommunications system is defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.

Telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system. An interactive telecommunications system is generally required as a condition of payment; however, section 1834(m)(1) of the Act allows the use of

asynchronous “store-and-forward” technology when the originating site is part of a federal telemedicine demonstration program in Alaska or Hawaii. As specified in regulations at § 410.78(a)(1), store-and-forward means the asynchronous transmission of medical information from an originating site to be reviewed at a later time by the practitioner at the distant site.

Medicare telehealth services may be furnished to an eligible telehealth individual notwithstanding the fact that the practitioner furnishing the telehealth service is not at the same location as the beneficiary. An eligible telehealth individual means an individual enrolled under Part B who receives a telehealth service furnished at an originating site.

Practitioners furnishing Medicare telehealth services are reminded that these services are subject to the same non-discrimination laws as other services, including the effective communication requirements for persons with disabilities of section 504 of the Rehabilitation Act and language access for persons with limited English proficiency, as required under Title VI of the Civil Rights Act of 1964. For more information, see <http://www.hhs.gov/ocr/civilrights/resources/specialtopics/hospitalcommunication>.

Practitioners furnishing Medicare telehealth services submit claims for telehealth services to the Medicare Administrative Contractors that process claims for the service area where their distant site is located. Section 1834(m)(2)(A) of the Act requires that a practitioner who furnishes a telehealth service to an eligible telehealth individual be paid an amount equal to the amount that the practitioner would have been paid if the service had been furnished without the use of a telecommunications system.

Originating sites, which can be one of several types of sites specified in the statute where an eligible telehealth individual is located at the time the service is being furnished via a telecommunications system, are paid a fee under the PFS for each Medicare telehealth service. The statute specifies both the types of entities that can serve as originating sites and the geographic qualifications for originating sites. With regard to geographic qualifications, § 410.78(b)(4) limits originating sites to those located in rural health professional shortage areas (HPSAs) or in a county that is not included in a metropolitan statistical areas (MSAs).

Historically, we have defined rural HPSAs to be those located outside of MSAs. Effective January 1, 2014, we modified the regulations regarding

originating sites to define rural HPSAs as those located in rural census tracts as determined by the Office of Rural Health Policy (ORHP) of the Health Resources and Services Administration (HRSA) (78 FR 74811). Defining “rural” to include geographic areas located in rural census tracts within MSAs allows for broader inclusion of sites within HPSAs as telehealth originating sites. Adopting the more precise definition of “rural” for this purpose expands access to health care services for Medicare beneficiaries located in rural areas. HRSA has developed a Web site tool to provide assistance to potential originating sites to determine their geographic status. To access this tool, see the CMS Web site at www.cms.gov/telehealth/.

An entity participating in a federal telemedicine demonstration project that has been approved by, or received funding from, the Secretary as of December 31, 2000 is eligible to be an originating site regardless of its geographic location.

Effective January 1, 2014, we also changed our policy so that geographic eligibility for an originating site would be established and maintained on an annual basis, consistent with other telehealth payment policies (78 FR 74400). Geographic eligibility for Medicare telehealth originating sites for each calendar year is now based upon the status of the area as of December 31 of the prior calendar year.

For a detailed history of telehealth payment policy, see 78 FR 74399.

2. Adding Services to the List of Medicare Telehealth Services

As noted previously, in the December 31, 2002 **Federal Register** (67 FR 79988), we established a process for adding services to or deleting services from the list of Medicare telehealth services. This process provides the public with an ongoing opportunity to submit requests for adding services. Under this process, we assign any qualifying request to make additions to the list of telehealth services to one of two categories. Revisions to criteria that we use to review requests in the second category were finalized in the November 28, 2011 **Federal Register** (76 FR 73102). The two categories are:

- **Category 1:** Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site

and, if necessary, the telepresenter, a practitioner with the beneficiary in the originating site. We also look for similarities in the telecommunications system used to deliver the proposed service; for example, the use of interactive audio and video equipment.

- **Category 2:** Services that are not similar to the current list of telehealth services. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of a telecommunications system to deliver the service produces demonstrated clinical benefit to the patient. In reviewing these requests, we look for evidence indicating that the use of a telecommunications system in furnishing the candidate telehealth service produces clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits.

Some examples of clinical benefit include the following:

- Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
- Treatment option for a patient population without access to clinically appropriate in-person treatment options.
- Reduced rate of complications.
- Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
- Decreased number of future hospitalizations or physician visits.
- More rapid beneficial resolution of the disease process treatment.
- Decreased pain, bleeding, or other quantifiable symptom.
- Reduced recovery time.

For the list of covered telehealth services, see the CMS Web site at www.cms.gov/telehealth/. Requests to add services to the list of Medicare telehealth services must be submitted and received no later than December 31 of each calendar year to be considered for the next rulemaking cycle. For example, qualifying requests submitted before the end of CY 2014 will be considered for the CY 2016 proposed rule. Each request to add a service to the

list of Medicare telehealth services must include any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as a vehicle for making changes to the list of Medicare telehealth services, requestors should be advised that any information submitted is subject to public disclosure for this purpose. For more information on submitting a request for an addition to the list of Medicare telehealth services, including where to mail these requests, see the CMS Web site at www.cms.gov/telehealth/.

3. Submitted Requests to the List of Telehealth Services for CY 2015

Under our existing policy, we add services to the telehealth list on a category 1 basis when we determine that they are similar to services on the existing telehealth list with respect to the roles of, and interactions among, the beneficiary, physician (or other practitioner) at the distant site and, if necessary, the telepresenter. As we stated in the CY 2012 final rule with comment period (76 FR 73098), we believe that the category 1 criteria not only streamline our review process for publicly requested services that fall into this category, the criteria also expedite our ability to identify codes for the telehealth list that resemble those services already on this list.

a. Submitted Requests

We received several requests in CY 2013 to add various services as Medicare telehealth services effective for CY 2015. The following presents a discussion of these requests, and our proposals for additions to the CY 2015 telehealth list. Of the requests received, we find that the following services are sufficiently similar to psychiatric diagnostic procedures or office/outpatient visits currently on the telehealth list to qualify on a category one basis. Therefore, we propose to add the following services to the telehealth list on a category 1 basis for CY 2015:

- CPT codes 90845 (Psychoanalysis); 90846 (family psychotherapy (without the patient present)); and 90847 (family psychotherapy (conjoint psychotherapy) (with patient present));
- CPT codes 99354 (prolonged service in the office or other outpatient setting requiring direct patient contact beyond the usual service; first hour (list separately in addition to code for office or other outpatient evaluation and management service)); and, 99355 (prolonged service in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (list

separately in addition to code for prolonged service); and,

- HCPCS codes G0438 (annual wellness visit; includes a personalized prevention plan of service (pps), initial visit; and, G0439 (annual wellness visit, includes a personalized prevention plan of service (pps), subsequent visit).

We also received requests to add services to the telehealth list that do not meet our criteria for being on the Medicare telehealth list. We did not propose to add the following procedures for the reasons noted:

- CPT codes 92250 (fundus photography with interpretation and report); 93010 (electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), 93307 (echocardiography, transthoracic, real-time with image documentation (2d), includes m-mode recording, when performed, complete, without spectral or color Doppler echocardiography; 93308 (echocardiography, transthoracic, real-time with image documentation (2d), includes m-mode recording, when performed, follow-up or limited study); 93320 (Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (list separately in addition to codes for echocardiographic imaging); complete); 93321 (Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (list separately in addition to codes for echocardiographic imaging); follow-up or limited study (list separately in addition to codes for echocardiographic imaging); and 93325 (Doppler echocardiography color flow velocity mapping (list separately in addition to codes for echocardiography). These services include a technical component (TC) and a professional component (PC). By definition, the TC portion of these services needs to be furnished in the same location as the patient and thus cannot be furnished via telehealth. The PC portion of these services could be (and typically would be) furnished without the patient being present in the same location. (Note: For services that have a TC and a PC, there is sometimes an entirely different code that is used when only the PC portion of the service is being furnished, and other times the same CPT code is used with a -26 modifier to indicate that only the PC is being billed.) For example, the interpretation by a physician of an actual electrocardiogram or electroencephalogram tracing that has been transmitted electronically, can be furnished without the patient being present in the same location as the physician. Given the nature of these services, it is not necessary to consider including the PC of these services for

addition to the telehealth list. When these PC services are furnished remotely, they do not meet the definition of Medicare telehealth services under section 1834(m) of the Act. Rather, these remote services are considered physicians' services in the same way as services that are furnished in-person without the use of telecommunications technology; they are paid under the same conditions as in-person physicians' services (with no requirements regarding permissible originating sites), and should be reported in the same way as other physicians' services (that is, without the -GT or -GQ modifiers).

- CPT codes 96103 (psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, eg, MMPI), administered by a computer, with qualified health care professional interpretation and report); and, 96120 (neuropsychological testing (eg, Wisconsin Card Sorting Test), administered by a computer, with qualified health care professional interpretation and report). These services involve testing by computer, can be furnished remotely without the patient being present, and are payable in the same way as other physicians' services. These remote services are not Medicare telehealth services as defined under the Act; therefore, we need not consider them for addition to the telehealth list, and the restrictions that apply to telehealth services do not apply to these services.

- CPT codes 90887 (interpretation or explanation of results of psychiatric, other medical examinations and procedures, or other accumulated data to family or other responsible persons, or advising them how to assist patient); 99090 (analysis of clinical data stored in computers (eg, ECGs, blood pressures, hematologic data); 99091 (collection and interpretation of physiologic data (eg, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time); 99358 (prolonged evaluation and management service before and/or after direct patient care; first hour); and 99359 (prolonged evaluation and management service before and/or after direct patient care; each additional 30 minutes (list separately in addition to code for prolonged service). These services are not separately payable by Medicare. It would be inappropriate to

include services as telehealth services when Medicare does not otherwise make a separate payment for them.

- CPT codes 96101 (psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, eg, MMPI, Rorschach, WAIS), per hour of the psychologist's or physician's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report); 96102 (psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, eg, MMPI and WAIS), with qualified health care professional interpretation and report, administered by technician, per hour of technician time, face-to-face); 96118 (neuropsychological testing (eg, Halstead-Reitan Neuropsychological Battery, Wechsler Memory Scales and Wisconsin Card Sorting Test), per hour of the psychologist's or physician's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report); and, 96119 (neuropsychological testing (eg, Halstead-Reitan Neuropsychological Battery, Wechsler Memory Scales and Wisconsin Card Sorting Test), with qualified health care professional interpretation and report, administered by technician, per hour of technician time, face-to-face). These services are not similar to other services on the telehealth list, as they require close observation of how a patient responds. The requestor did not submit evidence supporting the clinical benefit of furnishing these services on a category 2 basis. As such, we did not propose to add these services to the list of telehealth services.

- CPT codes 57452 (colposcopy of the cervix including upper/adjacent vagina; 57454 colposcopy of the cervix including upper/adjacent vagina; with biopsy(s) of the cervix and endocervical curettage); and, 57460 (colposcopy of the cervix including upper/adjacent vagina; with loop electrode biopsy(s) of the cervix). These services are not similar to other services on the telehealth service list. Therefore, it would not be appropriate to add them on a category 1 basis. The requestor did not submit evidence supporting the clinical benefit of furnishing these services on a category 2 basis. As such, we did not propose to add these services to the list of telehealth services.

- HCPCS code M0064 (brief office visit for the sole purpose of monitoring or changing drug prescriptions used in the treatment of mental psychoneurotic

and personality disorders) is being deleted for CY 2015. This code was created specifically to describe a service that is not subject to the statutory outpatient mental health limitation, which limited payment amounts for certain mental health services. Section 102 of the Medicare Improvements for Patients and Providers Act (Pub. L. 110–275, enacted on July 15, 2008) (MIPPA) required that the limitation on payment for outpatient mental health treatment to 62.5 percent of incurred expenses, in effect since the inception of the Medicare program, be reduced over four years. This limitation on payment for mental health treatment created a higher share of beneficiary coinsurance for these services than for most other Medicare services paid under the PFS. Effective January 1, 2014, 100 percent of expenses incurred for mental health treatment services are considered as incurred for purposes of Medicare, resulting in the same beneficiary cost sharing for these services as for other PFS services. Since the statute was amended to phase out the limitation, and the phase-out was complete effective January 1, 2014, Medicare no longer has a need to distinguish services subject to the mental health limitation from those that are not. Accordingly, the appropriate CPT code can now be used to bill Medicare for the services that would have otherwise been reported using M0064 and M0064 will be eliminated as a telehealth service, effective January 1, 2015.

- Urgent Dermatologic Problems and Wound Care—The American Telemedicine Association (ATA) cited several studies to support adding dermatology services to the telehealth list. However, the request did not include specific codes. Since we did not have specific codes to consider for this request, we cannot evaluate whether the services are appropriate for addition to the Medicare telehealth services list. We note that some of the services that the requester had in mind may be billed under the telehealth office visit codes or the telehealth consultation G-codes.

In summary, we proposed to add the following codes to the telehealth list on a category 1 basis:

- Psychotherapy services CPT codes 90845, 90846 and 90847.
- Prolonged service office CPT codes 99354 and 99355.
- Annual wellness visit HCPCS codes G0438 and G0439.

3. Modifying § 410.78 Regarding List of Telehealth Services

As discussed in section II.E.2. of this final rule with comment period, under the statute, we created an annual

process for considering the addition of services to the Medicare telehealth list. Under this process, we propose services to be added to the list in the proposed rule in response to public nominations or our own initiative and seek public comments on our proposals. After consideration of public comments, we finalize additions to the list in the final rule. We have also revised § 410.78(b) each year to include the description of the added services. Because the list of Medicare telehealth services has grown quite lengthy, and given the other mechanisms by which we can make the public aware of the list of Medicare telehealth services for each year, we proposed to revise § 410.78(b) by deleting the description of the individual services for which Medicare payment can be made when furnished via telehealth. Under this proposal, we would continue our current policy to address requests to add to the list of telehealth services through the PFS rulemaking process so that the public would have the opportunity to comment on additions to the list. We also proposed to revise § 410.78(f) to indicate that a list of Medicare telehealth codes and descriptors is available on the CMS Web site.

The following is a summary of the comments we received regarding the proposed addition of services to the list of Medicare telehealth services.

Comment: All commenters supported one or more of our proposals to add psychotherapy services (CPT codes 90845, 90846 and 90847); prolonged service office (CPT codes 99354 and 99355); and annual wellness visit (HCPCS codes G0438 and G0439) to the list of Medicare telehealth services for CY 2015.

Response: We appreciate the commenters' support for the proposed additions to the list of Medicare telehealth services. After consideration of the public comments received, we are finalizing our CY 2015 proposal to add these services to the list of telehealth services for CY 2015 on a category 1 basis.

Comment: Commenters also agreed with our rationale for rejecting other requested additions to the telehealth list. However, one commenter disagreed with our decision not to propose adding dermatology services, including those furnished using store-and-forward technology, to the list of telehealth services. Another commenter objected to our proposal not to add psychological testing services to the telehealth services list.

Response: As we noted in the proposed rule, the request to add dermatology services did not include

specific codes. Without specific codes to consider, we cannot evaluate whether the services are appropriate for addition to the Medicare telehealth services list. We note that some of the services that the requester had in mind may be billed under the telehealth office visit codes or the telehealth consultation G-codes.

Concerning payment for services furnished using store-and-forward technology, we note that the statute at section 1861(m) of the Act includes store-and-forward technology as a telecommunication system for telehealth services only in the case of federal telemedicine demonstration programs in Alaska and Hawaii (see § 410.78(d)).

Concerning psychological testing services, we noted that remote services (CPT codes 96103 and 96120) are not Medicare telehealth services as defined under the Act and thus can be furnished when beneficiary is not in the same place as the practitioner. It would also be counter-productive to add these codes to the telehealth list because, if we did, the telehealth originating site, geographic, and other restrictions would apply to these services.

CPT codes 90887, 90991, 93358 and 99359 are not separately payable by Medicare. It would be inappropriate to include services as telehealth services when Medicare does not otherwise make a separate payment for them.

Finally, CPT codes 96101, 96102, 96118 and 96119 are not similar to other services on the telehealth list, as they require close observation of how a patient responds. The requestor did not submit evidence supporting the clinical benefit of furnishing these services on a category 2 basis. As such, we did not propose to add these services to the list of telehealth services.

We received other public comments on matters related to Medicare telehealth services that were not the subject of proposals in the CY 2015 PFS proposed rule. Because we did not make any proposals regarding these matters, we generally do not summarize or respond to such comments in the final rule. However, we are summarizing and responding to the following comments to acknowledge the interests and concerns of the commenters, and a mechanism to address some of those concerns.

Many commenters supported the overall expansion of telehealth by:

- Removing geographic restrictions to include both rural and urban areas.
- Revising permissible originating sites to include a patient's home, domiciliary care and first responder vehicles.

- Adopting a broader definition of telehealth technologies to include services provide via mobile technology, including emails, phone calls, and store-and-forward technologies.

- Adding physical and occupational therapists as practitioners who can remotely furnish telehealth services.

- Adding more services to the telehealth list, including services under category 2.

- Prioritizing coverage of services that include care coordination with the patient's medical home and/or existing treating physicians.

- Considering the use of telehealth technology for the purpose of furnishing direct supervision of services furnished by on-site practitioners.

- Using demonstration projects under CMS's Center for Medicare and Medicaid Innovation (CMMI) to collect clinical evidence on the effect of expanding telehealth and to address how telemedicine can be integrated into new payment and delivery models.

Response: We appreciate the commenters' suggestions. As some commenters noted, we do not have authority to implement many of these revisions under the current statute. The CMS Innovation Center is responsible for developing and testing new payment and service delivery models to lower costs and improve quality for Medicare, Medicaid, and CHIP beneficiaries. As part of that authority, the CMS Innovation Center can consider potential new payment and service delivery models to test changes to Medicare's telehealth payment policies.

In summary, after consideration of the comments we received, we are finalizing our proposal to add psychotherapy services CPT codes 90845, 90846 and 90847; prolonged service office CPT codes 99354 and 99355; and annual wellness visit HCPCS codes G0438 and G0439 to the list of Medicare telehealth services.

In addition, we are finalizing our proposal to change our regulation at § 410.78(b) by deleting the description of the individual services for which Medicare payment can be made when furnished via telehealth. We will continue our current policy to address requests to add services to the list of Medicare telehealth services through the PFS rulemaking process so that the public has the opportunity to comment on additions to the list. We are also finalizing our proposal to revise § 410.78(f) to indicate that a list of Medicare telehealth codes and descriptors is available on the CMS Web site.

We remind all interested stakeholders that we are currently soliciting public

requests to add services to the list of Medicare telehealth services. To be considered during PFS rulemaking for CY 2016, these requests must be submitted and received by December 31, 2014. Each request to add a service to the list of Medicare telehealth services must include any supporting documentation the requester wishes us to consider as we review the request. For more information on submitting a request for an addition to the list of Medicare telehealth services, including where to mail these requests, we refer readers to the CMS Web site at www.cms.gov/telehealth/.

5. Telehealth Originating Site Facility Fee Payment Amount Update

Section 1834(m)(2)(B) of the Act establishes the Medicare telehealth originating site facility fee for telehealth services furnished from October 1, 2001, through December 31 2002, at \$20.00. For telehealth services furnished on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the MEI as defined in section 1842(i)(3) of the Act. The MEI increase for 2015 is 0.8 percent. Therefore, for CY 2015, the payment amount for HCPCS code Q3014 (Telehealth originating site facility fee) is 80 percent of the lesser of the actual charge or \$24.83. The Medicare telehealth originating site facility fee and MEI increase by the applicable time period is shown in Table 13.

TABLE 13—THE MEDICARE TELE-HEALTH ORIGINATING SITE FACILITY FEE AND MEI INCREASE BY THE APPLICABLE TIME PERIOD

Facility fee	MEI increase	Period
\$20.00 ...	N/A	10/01/2001–12/31/2002
20.60 ...	3.0	01/01/2003–12/31/2003
21.20 ...	2.9	01/01/2004–12/31/2004
21.86 ...	3.1	01/01/2005–12/31/2005
22.47 ...	2.8	01/01/2006–12/31/2006
22.94 ...	2.1	01/01/2007–12/31/2007
23.35 ...	1.8	01/01/2008–12/31/2008
23.72 ...	1.6	01/01/2009–12/31/2009
24.00 ...	1.2	01/01/2010–12/31/2010
24.10 ...	0.4	01/01/2011–12/31/2011
24.24 ...	0.6	01/01/2012–12/31/2012

TABLE 13—THE MEDICARE TELE-HEALTH ORIGINATING SITE FACILITY FEE AND MEI INCREASE BY THE APPLICABLE TIME PERIOD—Continued

Facility fee	MEI increase	Period
24.43 ...	0.8	01/01/2013–12/31/2013
24.63 ...	0.8	01/01/2014–12/31/2014
24.83 ...	0.8	01/01/2015–12/31/2015

F. Valuing New, Revised and Potentially Misvalued Codes

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS. Since inception of the PFS, it has also been a priority to revalue services regularly to assure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. Initially, this was accomplished primarily through the five-year review process, which resulted in revised RVUs for CY 1997, CY 2002, CY 2007, and CY 2012. Under the five-year review process, revisions in RVUs were proposed in a proposed rule and finalized in a final rule. In addition to the five-year reviews, in each year beginning with CY 2009, CMS and the RUC have identified a number of potentially misvalued codes using various identification screens, such as codes with high growth rates, codes that are frequently billed together, and high expenditure codes. Section 3134 of the Affordable Care Act codified the misvalued code initiative in section 1848(c)(2)(K) of the Act.

In the CY 2012 rulemaking process, we proposed and finalized consolidation of the five-year review and the potentially misvalued code activities into an annual review of potentially misvalued codes to avoid redundancies in these efforts and better accomplish our goal of assuring regular assessment of code values. Under the consolidated process, we issue interim final RVUs for all revaluations and new codes in the PFS final rule with comment period, and make payment based upon those values during the calendar year covered by the final rule. (Changes in the PFS methodology that may affect valuations of a variety of codes are issued as proposals in the proposed rule.) We consider and respond to any public comments on the interim final values in the final rule with comment period for the subsequent year. When consolidating these processes, we indicated that it was

appropriate to establish interim values for new, revised, and potentially misvalued codes because of the incongruity between the PFS rulemaking cycle and the release of codes by the AMA CPT Editorial Panel and the RUC review process. We stated that if we did not establish interim final values for revalued codes in the final rule with comment period, “a delay in implementing revised values for codes that have been identified as misvalued would perpetuate payment for the services at a rate that does not appropriately reflect the relative resources involved in furnishing the service and would continue unwarranted distortion in the payment for other services across the PFS.” We also reiterated that if we did not establish interim final values for new and revised codes, we would either have to delay the use of new and revised codes for one year, or permit each Medicare contractor to establish its own payment rate for these codes. We stated, “We believe it would be contrary to the public interest to delay adopting values for new and revised codes for the initial year, especially since we have an opportunity to receive significant input from the medical community [through the RUC] before adopting the values, and the alternatives could produce undesirable levels of uncertainty and inconsistency in payment for a year.”

1. Current Process for Valuing New, Revised, and Potentially Misvalued Codes

Under the process finalized in the CY 2012 PFS final rule with comment period, in each year’s proposed rule, we propose specific codes and/or groups of codes that we believe may be appropriate to consider under our potentially misvalued code initiative. As part of our process for developing the list of proposed potentially misvalued codes, we consider public nominations for potentially misvalued codes under a process also established in the CY 2012 PFS final rule with comment period. If appropriate, we include such codes in our proposed potentially misvalued code list. In the proposed rule, we solicit comments on the proposed potentially misvalued codes. We then respond to comments and establish a final list of potentially misvalued codes in the final rule for that year. These potentially misvalued codes are reviewed and revalued, if appropriate, in subsequent years. In addition, the RUC regularly identifies potentially misvalued codes using screens that have previously been identified by CMS, such as codes

performed together more than 75 percent of the time.

Generally, the first step in revaluing codes that have been identified as potentially misvalued is for the RUC to review these codes through its standard process, which includes active involvement of national specialty societies for the specialties that ordinarily use the codes. Frequently, the RUC’s discussion of potentially misvalued codes will lead the CPT Editorial Panel to make adjustments to the codes involved, such as bundling of codes, creation of new codes or revisions of code descriptors. The AMA has estimated that 75 percent of all annual CPT coding changes result from the potentially misvalued code initiative.

The RUC provides CMS with recommendations for the work values and direct PE inputs for the codes we have identified as potentially misvalued codes or, in the case of a coding revision, for the new or revised codes that will replace these potentially misvalued codes. (This process is also applied to codes that the RUC identifies using code screens that we have identified, and to new or revised codes that are issued for reasons unrelated to the potentially misvalued code process.) Generally, we receive the RUC recommendations concurrently for all codes in the same family as the potentially misvalued code(s). We believe it is important to evaluate and establish appropriate work and MP RVUs and direct PE inputs for an entire code family at the same time to avoid rank order anomalies and to maintain appropriate relativity among codes. We generally receive the RUC recommendations for the code or replacement code(s) within a year or two following the identification of the code as potentially misvalued.

We consider the RUC recommendations along with other information that we have, including information submitted by other stakeholders, and establish interim final RVUs for the potentially misvalued codes, new codes, and any other codes for which there are coding changes in the final rule with comment period for a year. There is a 60-day period for the public to comment on those interim final values after we issue the final rule. For services furnished during the calendar year following the publication of interim final rates, we pay for services based upon the interim final values established in the final rule. In the final rule with comment period for the subsequent year, we consider and respond to public comments received on the interim final values, and make

any appropriate adjustments to values based on those comments. We then typically finalize the values for the codes.

As we discussed in the CY 2012 PFS final rule with comment period, we adopted this consolidated review process to combine all coding revaluations into one annual process allowing for appropriate consideration of relativity in and across code families. In addition, this process assures that we have the benefit of the RUC recommendations for all codes being valued.

2. Concerns With Current Process

Some stakeholders who have experienced reductions in payments as the result of interim final valuations have objected to the process by which we revise or establish values for new, revised, and potentially misvalued codes. Some have stated that they did not receive notice of the possible reductions before they occurred. Generally, stakeholders are aware that we are considering changes in the payment rates for particular services either because CPT has made changes to codes or because we have identified the codes as potentially misvalued. As the RUC considers the appropriate value for a service, representatives of the specialties that use the codes are involved in the process. The RUC usually surveys physicians or other practitioners who furnish the services described by the codes regarding the time it takes to furnish the services, and representatives of the specialty(ies) also participate in the RUC meetings where recommendations for work RVUs and direct PE inputs are considered. Through this process, representatives of the affected specialties are generally aware of the RUC recommendations.

Some stakeholders have stated that even when they are aware that the RUC has made recommendations, they have no opportunity to respond to the RUC recommendations before we consider them in adopting interim final values because the RUC actions and recommendations are not public. Some stakeholders have also said that the individuals who participate in the RUC review process are not able to share the recommendations because they have signed a confidentiality agreement. We note, however, that at least one specialty society has raised funds via its Web site to fight a “pending cut” based upon its knowledge of RUC recommendations for specific codes prior to CMS action on the recommendation. Additionally, some stakeholders have pointed out that some types of suppliers that are paid

under the PFS are not permitted to participate in the RUC process at all.

We recognize that some stakeholders, including those practitioners represented by societies that are not participants in the RUC process, may not be aware of the specifics of the RUC recommendations before we consider them in establishing interim final values for new, revised, and potentially misvalued codes. We note that, as described above, before we review a service as a potentially misvalued code, we go through notice and comment rulemaking to identify it as a potentially misvalued code. Thus, the public has notice and an opportunity to comment on whether we should review the values for a code before we finalize the code as potentially misvalued and begin the valuation process. As a result, all stakeholders should be aware that a particular code is being considered as potentially misvalued and that we may establish revised interim final values in a subsequent final rule with comment period. As noted above, there may be some codes for which we receive RUC recommendations based upon their identification by the RUC through code screens that we establish. These codes are not specifically identified by CMS through notice and comment rulemaking as potentially misvalued codes. We recognize that if stakeholders are not monitoring RUC activities or evaluating Medicare claims data, they may be unaware that these codes are being reviewed and could be revalued on an interim final basis in a final rule with comment period for a year.

In recent years, we have increased our scrutiny of the RUC recommendations and have increasingly found cause to modify the values recommended by the RUC in establishing interim final values under the PFS. Sometimes we also find it appropriate, on an interim final basis, to refine how the CPT codes are to be used for Medicare services or to create G-codes for reporting certain services to Medicare. Some stakeholders have objected to such interim final decisions because they do not learn of the CMS action until the final rule with comment period is issued. Stakeholders said that they do not have an opportunity to meaningfully comment and for CMS to address their comments before the coding or valuation decision takes effect.

We received comments on the CY 2014 PFS final rule with comment period suggesting that the existing process for review and adoption of interim final values for new, revised, and misvalued codes violates section 1871(a)(2) of the Act, which prescribes the rulemaking requirements for the

agency in establishing payment rates. In response to those commenters, we note that the process we use to establish interim final rates is in full accordance with the statute and we do not find this a persuasive reason to consider modifying the process that we use to establish PFS rates.

Our recent revaluation of the four epidural injection codes provides an example of the concerns that have been expressed with the existing process. In the CY 2014 PFS final rule with comment period, we established interim final values for four epidural injection codes, which resulted in payment reductions for the services when furnished in the office setting of between 35 percent and 56 percent. (In the facility setting, the reductions ranged from 17 percent to 33 percent.) One of these codes had been identified as a potentially misvalued code 2 years earlier. The affected specialties had been involved in the RUC process and were generally aware that the family of codes would be revalued on an interim basis in an upcoming rule. They were also aware that the RUC had made significant changes to the direct PE inputs, including removal of the radiographic-fluoroscopy room, which explains, in large part, the reduction to values in the office setting. The societies representing the affected specialty were also aware of significant reductions in the RUC-recommended “time” to furnish the procedures based on the most recent survey of practitioners who furnish the services, which resulted in reductions in both the work and PE portion of the values. Although the specialties were aware of the changes that the RUC was recommending to direct PE inputs, they were not specifically aware of how those changes would affect the values and payment rate. In addition, we decreased the work RVUs for these procedures because we found the RUC-recommended work RVUs did not adequately reflect the RUC-recommended decreases in time. This decision is consistent with our general practice when the best available information shows that the time involved in furnishing the service has decreased, and in the absence of information suggesting an increase in work intensity. Since the interim final values for these codes were issued in the CY 2014 PFS final rule with comment period, we have received numerous comments that will be useful to us as we consider finalizing values for these codes. If we had followed a process that involved proposing values for these codes in a proposed rule, we would have been able to consider the

additional information contained in these comments prior to making payments for the services based upon revised values. (See section II.B.3.b.(2) of this final rule with comment period for a discussion of proposed valuation of these epidural injection codes for CY 2015.)

3. Alternatives to the Current Process

In the proposed rule, we noted that given our heightened review of the RUC recommendations and the increased concerns expressed by some stakeholders, we believed that an assessment of our process for valuing these codes was warranted. To that end, we considered potential alternatives to address the timing and rulemaking issues associated with establishing values for new, revised and potentially misvalued codes (as well as for codes within the same families as these codes). Specifically, we explored three alternatives to our current approach:

- Propose work and MP RVUs and direct PE inputs for all new, revised and potentially misvalued codes in a proposed rule.

- Propose changes in work and MP RVUs and direct PE inputs in the proposed rule for new, revised, and potentially misvalued codes for which we receive RUC recommendations in time; continue to establish interim final values in the final rule for other new, revised, and potentially misvalued codes.

- Increase our efforts to make available more information about the specific issues being considered in the course of developing values for new, revised and potentially misvalued codes to increase transparency, but without making changes to the existing process for establishing values.

In the proposed rule we discussed each of these alternatives as follows.

(a) *Propose work and MP RVUs and direct PE inputs for new, revised, and potentially misvalued codes in the proposed rule:*

Under this approach, we stated that we would evaluate the RUC recommendations for all new, revised, and potentially misvalued codes, and include proposed work and MP RVUs and direct PE inputs for the codes in the first available PFS proposed rule. We would receive and consider public comments on those proposals and establish final values in the final rule. The primary obstacle to this approach relates to the current timing of the CPT coding changes and RUC activities. Under the current calendar, all CPT coding changes and most RUC recommendations are not available to us in time to include proposed values for

all codes in the proposed rule for that year.

Therefore, we stated that if we were to adopt this proposal, which would require us to propose changes in inputs before we revalue codes based upon those values, we would need a mechanism to pay for services for which the existing codes would no longer be available, or for which there would be changes for a given year.

As we noted in the CY 2012 PFS final rule with comment period, the RUC recommendations are an essential element that we consider when valuing codes. Likewise, we recognize the significant contribution that the CPT Editorial Panel makes to the success of the potentially misvalued code initiative through its consideration and adoption of coding changes. Although we have increased our scrutiny of the RUC recommendations in recent years and accepted fewer of the recommendations without making our own refinements, the CPT codes and the RUC recommendations continue to play a major role in our valuations. For many codes, the surveys conducted by specialty societies as part of the RUC process are the best data that we have regarding the time and intensity of work. The RUC determines the criteria and the methodology for those surveys. It also reviews the survey results. This process allows for development of survey data that are more reliable and comparable across specialties and services than would be possible without having the RUC at the center of the survey vetting process. In addition, the debate and discussion of the services at the RUC meetings in which CMS staff participate provides a good understanding of what the service entails and how it compares to other services in the family, and to services furnished by other specialties. The debate among the specialties is also an important part of this process. Although we increasingly consider data and information from many other sources, and we intend to expand the scope of those data and sources, the RUC recommendations remain a vital part of our valuation process.

Thus, if we were to adopt this approach, we would need to address how to make payment for the services for which new or revised codes take effect for the following year but for which we did not receive RUC recommendations in time to include proposed work values and PE inputs in the proposed rule. Because the annual coding changes are effective on January 1st of each year, we would need a mechanism for practitioners to report services and be paid appropriately

during the interval between the date the code takes effect and the time that we receive RUC recommendations and complete rulemaking to establish values for the new and revised codes. One option would be to establish G-codes with identical descriptors to the predecessors of the new and revised codes and, to the fullest extent possible, carry over the existing values for those codes. This would effectively preserve the status quo for one year.

The primary advantage of this approach would be that the RVUs for all services under the PFS would be established using a full notice and comment procedure, including consideration of the RUC recommendations, before they take effect. In addition to having the benefit of the RUC recommendations, this would provide the public the opportunity to comment on a specific proposal prior to it being implemented. This would be a far more transparent process, and would assure that we have the full benefit of stakeholder comments before establishing values.

One drawback to such a process is that the use of G-codes for a significant number of codes may create an administrative burden for CMS and for practitioners. Presumably, practitioners would need to use the G-codes to report certain services for purposes of Medicare, but would use the new or revised CPT codes to report the same services to private insurers. The number of G-codes needed each year would depend on the number of CPT code changes for which we do not receive the RUC recommendations in time to formulate a proposal to be included in the proposed rule for the year. To the extent that we receive the RUC recommendations for all new and revised codes in time to develop proposed values for inclusion in the proposed rule, there would be no need to use G-codes for this purpose.

Another drawback is that we would need to delay for at least one year the revision of values for any misvalued codes for which we do not receive RUC recommendations in time to include a proposal in the proposed rule. For a select set of codes, we would be continuing to use the RVUs for the codes for an additional year even though we know they do not reflect the most accurate resources. Since the PFS is a budget neutral system, misvalued services affect payments for all services across the fee schedule. On the other hand, if we were to take this approach, we would have the full benefit of public comments received on the proposed values for potentially misvalued

services before implementing any revisions.

(b) *Propose changes in work and MP RVUs and PE inputs in the proposed rule for new, revised, and potentially misvalued codes for which we receive RUC recommendations in time; continue to establish interim final values in the final rule for other new, revised, and potentially misvalued codes:*

This alternative approach would allow for notice and comment rulemaking before we adopt values for some new, revised and potentially misvalued codes (those for which we receive RUC recommendations in time to include a proposal in the proposed rule), while others would be valued on an interim final basis (those for which we do not receive the RUC recommendations in time). Under this approach, we would establish values in a year for all new, revised, and potentially misvalued codes, and there would be no need to provide for a mechanism to continue payment for outdated codes pending receipt of the RUC recommendations and completion of a rulemaking cycle. For codes for which we do not receive the RUC recommendations in time to include a proposal in the proposed rule for a year, there would be no change from the existing valuation process.

This would be a balanced approach that recognizes the benefits of a full opportunity for notice and comment rulemaking before establishing rates when timing allows, and the importance of establishing appropriate values for the current version of CPT codes and for potentially misvalued codes when the timing of the RUC recommendations does not allow for a full notice and comment procedure.

However, this alternative would go only part of the way toward addressing concerns expressed by some stakeholders. For those codes for which the RUC recommendations are not received in time for us to include a proposal in the proposed rule, Medicare payment for one year would still be based on inputs established without the benefit of full public notice and comment. Another concern with this approach is that it could lead to the valuation of codes within the same family at different times depending on when we receive RUC recommendations for each code within a family. As discussed previously, we believe it is important to value an entire code family together to make adjustments to account appropriately for relativity within the family and between the family and other families. If we receive RUC recommendations in time to propose

values for some, but not for all, codes within a family, we would respond to comments in the final rule to establish final values for some of the codes while adopting interim final values for other codes within the same family. The differences in the treatment of codes within the same family could limit our ability to value codes within the same family with appropriate relativity. Moreover, under this alternative, the main determinant of how a code would be handled would be the timing of our receipt of the RUC recommendation for the code. Although this approach would offer stakeholders the opportunity to comment on specific proposals in the proposed rule, the adoption of changes for a separate group of codes in the final rule could significantly change the proposed values simply due to the budget neutrality adjustments due to additional codes being valued in the final rule.

(c) Increase our efforts to make available more information about the specific issues being considered in the course of developing values for new, revised and potentially misvalued codes in order to increase transparency, but without a change to the existing process for establishing values:

The main concern with continuing our current approach is that stakeholders have expressed the desire to have adequate and timely information to permit the provision of relevant feedback to CMS for our consideration prior to establishing a payment rate for new, revised, and potentially misvalued codes. We could address some aspects of this issue by increasing the transparency of the current process. Specifically, we could make more information available on the CMS Web site before interim final values are established for codes. Examples of such information include an up-to-date list of all codes that have been identified as potentially misvalued, a list of all codes for which RUC recommendations have been received, and the RUC recommendations for all codes for which we have received them.

Although the posting of this information would significantly increase transparency for all stakeholders, it still would not allow for full notice and comment rulemaking procedures before values are established for payment purposes. Nor would it provide the public with advance information about whether or how we will make refinements to the RUC recommendations or coding decisions in the final rule with comment period. Thus, stakeholders would not have an opportunity to provide input on our

potential modifications before interim final values are adopted.

4. Proposal To Modify the Process for Establishing Values for New, Revised, and Potentially Misvalued Codes

After considering the current process, including its strengths and weaknesses, and the alternatives to the current process described previously, we proposed to modify our process to make all changes in the work and MP RVUs and the direct PE inputs for new, revised and potentially misvalued services under the PFS by proposing the changes in the proposed rule, beginning with the PFS proposed rule for CY 2016. We proposed to include proposed values for all new, revised and potentially misvalued codes for which we have complete RUC recommendations by January 15th of the preceding year. We also proposed to delay revaluing the code for one year (or until we receive RUC recommendations for the code before January 15th of a year) and include proposed values in the following year's rule if the RUC recommendation was not received in time for inclusion in the proposed rule. Thus, we would include proposed values prior to using the new code (in the case of new or revised codes) or revising the value (in the case of potentially misvalued codes). Due to the complexities involved in code changes and rate setting, there could be some circumstances where, even when we receive the RUC recommendations by January 15th of a year, we are not able to propose values in that year's proposed rule. For example, we might not have recommendations for the whole family or we might need additional information to appropriately value these codes. In situations where it would not be appropriate or possible to propose values for certain new, revised, or potentially misvalued codes, we would treat them in the same way as those for which we did not receive recommendations before January 15th.

For new, revised, and potentially misvalued codes for which we do not receive RUC recommendations before January 15th of a year, we proposed to adopt coding policies and payment rates that conform, to the extent possible, to the policies and rates in place for the previous year. We would adopt these conforming policies on an interim basis pending our consideration of the RUC recommendations and the completion of notice and comment rulemaking to establish values for the codes. For codes for which there is no change in the CPT code, it is a simple matter to continue the current valuation. For services for which there are CPT coding changes, it

is more complicated to maintain the current payment rates until the codes can be valued through the notice and comment rulemaking process. Since the changes in CPT codes are effective on January 1st of a year, and we would not have established values for the new or revised codes (or other codes within the code family), it would not be practical for Medicare to use those CPT codes. For codes that were revised or deleted as part of the annual CPT coding changes, when the changes could affect the value of a code and we have not had an opportunity to consider the relevant RUC recommendations prior to the proposed rule, we propose to create G-codes to describe the predecessor codes to these codes. If CPT codes are revised in a manner that would not affect the resource inputs used to value the service (for example, a grammatical changes to CPT code descriptors), we could use these revised codes and continue to pay at the rate developed through the use of the same resource inputs. For example, if a single CPT code was separated into two codes and we did not receive RUC recommendations for the two codes before January 15th of the year, we would assign each of those new codes an "I" status indicator (which denotes that the codes are "not valid for Medicare purposes"), and those codes could not be used for Medicare payment during the year. Instead, we would create a G-code with the same description as the single predecessor CPT code and continue to use the same inputs as the predecessor CPT code for that G-code during the year.

For new codes that describe wholly new services, as opposed to new or revised codes that are created as part of a coding revision of a family or that describe services already on the PFS, we would make every effort to work with the RUC to ensure that we receive recommendations in time to include proposed values in the proposed rule. However, if we do not receive timely recommendations from the RUC for such a code and we determine that it is in the public interest for Medicare to use a new code during the code's initial year, we would establish values for the code's initial year. As we do under our current policy, if we receive the RUC recommendations in time to consider them for the final rule, we propose to establish values for the initial year on an interim final basis subject to comment in the final rule. In the event we do not receive RUC recommendations in time to consider them for the final rule, or in other situations where it would not be appropriate to establish interim final

values (for example, because of a lack of necessary information about the work or the price of the PE inputs involved), we would contractor price the code for the initial year.

We specifically sought comments on the following topics:

- Is this proposal preferable to the present process? Is another one of the alternatives better?
- If we were to implement this proposal, is it better to move forward with the changes, or is more time needed to make the transition such that implementation should be delayed beyond CY 2016? What factors should we consider in selecting an implementation date?
- Are there alternatives other than the use of G-codes that would allow us to address the annual CPT changes through notice and comment rather than interim final rulemaking?

Comment: The vast majority of commenters support a process, such as the one we proposed, that would result in having an opportunity for public comment on specific CMS proposals to change rates prior to payments being made based upon those rates. Commenters supporting a more transparent process include most medical organizations. MedPAC supported including proposals for rate changes in the proposed rule, but disagreed with preserving existing rates when RUC recommendations were not received in time to value in the proposed rule stating that this perpetuates paying at rates that we know are misvalued. As an alternative, MedPAC suggested that for codes for which we received RUC recommendations after the deadline for the proposed rule, we establish interim final values using the existing process. MedPAC also encouraged us to work with the CPT Editorial Panel and the RUC to better disseminate information about coding and payment recommendations that might be used for interim values as far in advance as possible. Several commenters who do not currently participate in the development of RUC recommendations suggested that we require the RUC to make its operations more transparent. Most of the commenters that supported the proposal also suggested making at least some modifications to the proposal. Some commenters indicated there was no need for a change from the current process. Another commenter stated “CMS’s proposal is overly complex, potentially burdensome, and goes well beyond the principal request of the medical specialty societies and Congress—that is, for CMS to publish reimbursement changes for misvalued

codes in the proposed rule, as opposed to waiting until the final rule.”

Response: We appreciate the many comments in support of our proposal to be more transparent in our ratesetting process by including proposed changes in inputs for new, revised, and potentially misvalued codes in the PFS proposed rules each year. We received only minimal comments on the other alternatives we presented, and only one comment suggesting that the current process was ideal and should be maintained. Thus, we are finalizing the proposal, with the modifications discussed below, to change our process for establishing values for new, revised, and potentially misvalued codes each year by proposing values for them in the proposed rule. We note that the CPT Editorial Panel and the RUC have made significant efforts in recent years to make their processes more transparent, such as making minutes of meetings publicly available. We encourage them to continue these efforts and also to consider ways that all physicians, practitioners and other suppliers paid under the PFS are aware of issues that are being considered by the RUC, and have an opportunity to provide input. With regard to comments suggesting that we propose values for some codes in the proposed rule and establish values for others as interim final in the final rule with comment period, as we discussed in making the proposal, we believe this type of system has several flaws. Most significantly, since the PFS is a budget neutral system, proposals are more meaningful when they can be considered in relation to all codes being revalued in a year in order to allow public comment on the entire fee schedule at one time. Additionally, we believe it is difficult to justify the presence or absence of an opportunity for public comment in advance of our adopting and using new values and inputs for services when the outcome essentially depends upon when we receive RUC recommendations.

Comment: Commenters expressed mixed opinions on when the new process should begin. The AMA, the RUC, and most medical specialties opposed the proposed CY 2016 implementation and asked that it be delayed until CY 2017. Commenters supporting a delay suggested that much work had already been done for the CY 2016 coding cycle in anticipation that these codes could be used for CY 2016, and stated it seems unfair to now delay valuing these codes because the process is being changed. These commenters also suggested that by delaying until CY 2017, the CPT Editorial Panel and the RUC would have time to adjust their

agendas and workload so as to provide more recommendations in time for the proposed rule. By contrast, several commenters, including those with major code revisions for CY 2015, such as codes for radiation therapy and upper gastrointestinal procedures, suggested that we should implement the new process immediately, and thus, delay implementation of the new code sets and values so that they could be issued as proposals in the CY 2016 proposed rule. Although each of the commenters took some unique positions in supporting a delay, they emphasized the importance of the opportunity to comment on our specific proposals for valuation as a major consideration for the delay. A few other commenters also suggested that the benefit of the opportunity for public comment prior to changing values warrants immediate implementation. Some commenters supported a CY 2016 implementation date as we proposed. A small group of commenters suggested an interim approach under which, for CY 2016, we would publish “some, but not all, values” in the proposed rule and use the interim final approach for others.

Response: After reviewing the comments, we understand that the implementation of a new process such as this one will affect stakeholders in differing ways. As we consider the most appropriate time frame for implementation, we believe that flexibility in implementation offers the optimal solution. Accordingly, we are delaying the adoption of two new codes sets (radiation therapy and lower gastrointestinal endoscopies) until CY 2016 as requested by affected stakeholders so that those most affected by these significant changes have the opportunity to comment on our proposals for valuing these codes sets before they are implemented. (See section II.G.3 of this final rule.)

Similarly, as requested by the AMA and most other medical specialty societies, we are delaying the complete implementation of this process so that those who have requested new codes and modifications in existing codes with the expectation that they would be valued under the PFS for CY 2016 will not be negatively affected by timing of this change. We note that the AMA has been working to develop timeframes that would allow a much higher percentage of codes to be addressed in the proposed rule, and has shared with us some plans to achieve this goal. We appreciate AMA’s efforts and are confident that with the finalization of this process, the CPT Editorial Panel and the RUC will be able to adjust their timelines and processes so that most, if

not all, of the annual coding changes and valuation recommendations can be addressed in the proposed rule prior to the effective date of the coding changes. This delay in implementation will provide additional time for these bodies to adjust their agendas and the timing of their recommendations to CMS to more appropriately align with the new process. As suggested by some commenters, we will use CY 2016 as a transition year. In the PFS proposed rule for CY 2016, we will propose values for the new, revised and potentially misvalued codes for which we receive the RUC recommendations in time for inclusion in the CY 2016 proposed rule. We will also include proposals for the two code sets delayed from CY 2015 in the CY 2016 proposed rule, as discussed above. For those new, revised, and potentially misvalued codes for which we do not receive RUC recommendations in time for inclusion in the proposed rule, we anticipate establishing interim final values for them for CY 2016, consistent with the current process. Beginning with valuations for CY 2017, the new process will be applicable to all codes. In other words, beginning with rulemaking for CY 2017, we will propose values for the vast majority of new, revised, and potentially misvalued codes and consider public comments before establishing final values for the codes; use G-codes as necessary in order to facilitate continued payment for certain services for which we do not receive RUC recommendations in time to propose values; and adopt interim final values in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive RUC recommendations in time to propose values. Consistent with this policy, we are finalizing our proposed regulatory change to § 414.24 with the addition of the phrase "For valuations for calendar year 2017 and beyond," to paragraph (b) to reflect the implementation for all CY 2017 valuations."

Comment: Commenters also addressed the January 15th deadline for valuations to be considered for the proposed rule. The AMA recommended a deadline of 30 days after the RUC's January meeting to allow time to submit complete recommendations for the proposed rule. Many others supported this, with some commenters suggesting a variety of dates between January 31st and April. Commenters suggested using an April deadline so that we could include the recommendations from the April RUC meeting in the proposed rule.

Response: In proposing a deadline for inclusion in the proposed rule, we

attempted to strike a balance that allows CMS adequate time for CMS to do a thorough job in vetting recommendations and formulating proposals, and allows the RUC as much time as possible to complete its activities. Review of RUC recommendations and application of the PFS methodology to particular codes requires significant time to complete. With new statutory requirements being implemented in CY 2017, such as those requiring multi-year transitions of certain changes in values and modification to PFS payments if specified targets are not met, we believe we will need more time to complete the process of formulating proposals. We believe that we need to establish a consistent deadline for receipt of RUC recommendations in order to allow all stakeholders and CMS to plan appropriately. To balance competing priorities, we are finalizing a deadline of February 10th. Our ability to complete our work in this more limited time will depend in large part on the volume of recommendations handled at the last RUC meeting and when we receive those recommendations. We are seeking the RUC's assistance in minimizing the recommendations that we receive after the beginning of the year.

Comment: The majority of commenters opposed the use of G-codes, primarily citing the administrative burden of having to use a separate set of codes for Medicare claims. One commenter called the G-code proposal "unworkable." In addition, MedPAC objected to the principal of attempting to maintain rates that are known to be misvalued. Those supporting the use of G-codes generally recognized the administrative burden, but believed the importance of the opportunity for public comment on proposed values before they take effect outweighed the administrative inconvenience. Commenters urged us to minimize the use of G-codes.

Response: We recognize the commenters' concerns with the use of G-codes. We agree that it is preferable to use CPT codes whenever possible. Under our finalized process, the use of G-codes for the purpose of holding over current coding and payment policies should not be necessary, generally, as long as we receive RUC recommendations for all new, revised and potentially misvalued codes before February 10th of the prior year. However, we need to preserve our ability to establish a proxy for current coding and values in situations where we receive the RUC recommendations too late or, for some other reason, encounter serious difficulty developing

proposed values for revised code sets. In the proposed rule, we sought input as to ways to achieve this without using G-codes. The only suggestion offered by commenters was to value such codes on an interim final basis. As we discuss above, we believe the program and its stakeholders are better served by delaying revaluations for one year while we used the notice and comment process to obtain public comments in advance. The comments on this proposal were overall overwhelming supportive of this point of view. Accordingly, we are not foreclosing the possibility of using G-codes for this purpose when warranted by the circumstances. However, we are cognizant of the difficulties created by the use of G-codes and will seek to minimize their use. We also note that the RUC and stakeholders can assist us in minimizing the use of G-codes by taking steps to insure that we receive RUC recommendations as early as possible.

5. Refinement Panel

As discussed in the 1993 PFS final rule with comment period (57 FR 55938), we adopted a refinement panel process to assist us in reviewing the public comments on CPT codes with interim final work RVUs for a year and in developing final work values for the subsequent year. We decided the panel would be comprised of a multispecialty group of physicians who would review and discuss the work involved in each procedure under review, and then each panel member would individually rate the work of the procedure. We believed establishing the panel with a multispecialty group would balance the interests of the specialty societies who commented on the work RVUs with the budgetary and redistributive effects that could occur if we accepted extensive increases in work RVUs across a broad range of services.

Following enactment of section 1848(c)(2)(K) of the Act, which required the Secretary periodically to review potentially misvalued codes and make appropriate adjustments to the RVUs, we reassessed the refinement panel process. As detailed in the CY 2011 PFS final rule with comment period (75 FR 73306), we continued using the established refinement panel process with some modifications.

As we considered making changes to the process for valuing codes, we reassessed the role that the refinement panel process plays in the code valuation process. We noted that the current refinement panel process is tied to interim final values. It provides an opportunity for stakeholders to provide

new clinical information that was not available at the time of the RUC valuation that might affect work RVU values that are adopted in the interim final value process. We noted that if our proposal to modify the valuation process for new, revised, and potentially misvalued codes is adopted, there would no longer be interim final values except for very few codes that describe totally new services. Thus, we proposed eliminating the refinement panel process.

We also noted that by using the proposed process for new, revised, and potentially misvalued codes, we believed the consideration of additional clinical information and any other issues associated with the CMS proposed values could be addressed through the notice and comment process. Similarly, prior to CY 2012 when we consolidated the five-year valuation, changes made as part of the five-year review process were addressed in the proposed rule and those codes were generally not subject to the refinement process. The notice and comment process would provide stakeholders with complete information on the basis and rationale for our proposed inputs and any relating coding policies. We also noted that an increasing number of requests for refinement do not include new clinical information that would justify a change in the work RVUs and that was not available at the time of the RUC meeting, in accordance with the current criteria for refinement. Thus, we did not believe the elimination of the refinement panel process would negatively affect the code valuation process. We believe the proposed process, which includes a full notice and comment procedure before values are used for purposes of payment, offers stakeholders a better mechanism for providing any additional data for our consideration and discussing any concerns with our proposed values than the current refinement process.

Comment: We received many comments on our proposal to eliminate the refinement panel, but most addressed problems with the existing refinement process and suggested improvements and alternatives rather than reasons not to eliminate the refinement panel. Concerns with the refinement panel process included that CMS imposed too high a standard for referring codes to refinement and that CMS decreasingly changed values based upon the refinement panel results. Some noted that organizations with limited resources are disadvantaged compared to those with significant resources to overturn any CMS interim final values

without a refinement process. In addition, some commenters stated that elimination of the refinement panel runs contrary to the transparency that CMS is trying to achieve. Many discussed their previous understanding that the refinement panel was essentially an appeals process for interim final values.

Commenters supported “a fair, objective, and consistently applied appeals process that would be open to any commenting organization.” Commenters expressed concern that the elimination of the refinement panel without a replacement mechanism “indicates that CMS will no longer seek the independent advice of contractor medical officers and practicing physicians and will solely rely on Agency staff to determine if the comment is persuasive in modifying a proposed value. The lack of any perceived organized appeal process will likely lead to a fragmented lobbying effort, rather than an objective review process.”

MedPAC suggested that we use a panel with membership limited to those without a financial stake in the process, such as contractor medical directors, experts in medical economics and technology diffusion, private payer representatives, and a mix of physicians and other health professionals not directly affected by the RVUs in question. It also suggested user fees to provide the resources needed or such a refinement panel.

Response: We acknowledge the commenters’ concerns and believe that some of the dissatisfaction with the current refinement panel mechanism stems from the expectation that it constitutes an appeals process. We do not agree. We believe the purpose of the refinement panel is to give us additional information to consider in exercising our responsibility to establish appropriate RVUs for Medicare services. Like many of the commenters, we believe the refinement panel is not achieving its purpose. Rather than providing us with additional information to assist us in establishing work RVUs, most often the refinement panel discussion reiterates the issues raised and information discussed at the RUC. Since we had access to this information at the time interim final values were established, it seems unlikely that a repeat discussion of the same issues would lead us to change valuations based upon information that already had been carefully considered. We remain concerned about the amount of resources devoted to refinement panel activities as compared to the benefit received. However, in light of the significant concerns raised by

commenters, we are not finalizing our proposal to eliminate the refinement panel. We will use the refinement panel for consideration of interim final rates for CY 2015 under the existing rules. We will also explore ways to address the many concerns that we and stakeholders have about the refinement panel process and whether the change in process eliminates the need for a refinement panel.

We are also finalizing our proposed change to the regulation at § 414.24 with the addition of the phrase “For valuations for calendar year 2017 and beyond,” to paragraph (b) to reflect implementation of the revised process for all valuations beginning with those for CY 2017.

G. Establishing RVUs for CY 2015

1. Methodology

We conducted a review of each code identified in this section and reviewed the current work RVU, if one exists, the RUC-recommended work RVUs, intensity, and time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our review generally includes, but is not limited to, a review of information provided by the RUC, Health Care Professionals Advisory Committee (HCPAC), and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the Medicare PFS, consultation with other physicians and health care professionals within CMS and the federal government. We also assessed the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalk to key reference or similar codes, and magnitude estimation. More information on these issues is available in that rule. When referring to a survey, unless otherwise noted, we mean the surveys conducted by specialty societies as part of the formal RUC process. The building block methodology is used to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code. Components used in the building block approach may include preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the components could be the CPT

codes that make up the bundled code. Magnitude estimation refers to a methodology for valuing physician work that determines the appropriate work RVU for a service by gauging the total amount of physician work for that service relative to the physician work for similar service across the PFS without explicitly valuing the components of that work.

The PFS incorporates cross-specialty and cross-organ system relativity. Valuing services requires an assessment of relative value and takes into account the clinical intensity and time required to furnish a service. In selecting which methodological approach will best determine the appropriate value for a service, we consider the current and recommended work and time values, as well as the intensity of the service, all relative to other services.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently there are six preservice time packages for services typically furnished in the facility setting, reflecting the different combinations of straightforward or difficult procedure, straightforward or difficult patient, and without or with sedation/anesthesia. Currently, there are three preservice time packages for services typically furnished in the nonfacility setting, reflecting procedures without and with sedation/anesthesia care. We have developed several standard building block methodologies to appropriately value services when they have common billing patterns. In cases where a service is typically furnished to a beneficiary on the same day as an evaluation and management (E/M) service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. We believe that at least one-third of the physician time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit. Accordingly, in cases where we believe that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we adjust the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service times the intensity of the work. Preservice evaluation time and postservice time both have a long-

established intensity of work per unit of time (IWPOT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU. Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes \times 0.0224 IWPOT) if we do not believe the overlap in time has already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, addresses the overlap in time and work when a service is typically provided on the same day as an E/M service. The RVUs and other payment information for all CY 2015 payable codes are available in Addendum B. The RVUs and other payment information for all codes subject to public comment are available in Addendum C. Both addenda are available on the CMS Web site under downloads for the CY 2015 PFS final rule with comment period at <http://www.cms.gov/physicianfeesched/downloads/>. The time values for all CY 2015 codes are listed in a file called "CY 2015 PFS Physician Time," available on the CMS Web site under downloads for the CY 2015 PFS final rule with comment period at <http://www.cms.gov/physicianfeesched/downloads/>.

2. Addressing CY 2014 Interim Final RVUs

In this section, we are responding to the public comments received on specific interim final values established in the CY 2014 PFS final rule with comment period and discussing the final values that we are establishing for CY 2015. The final CY 2015 work, PE, and MP RVUs are in Addendum B of a file called "CY 2015 PFS Addenda," available on the CMS Web site under downloads for the CY 2015 PFS final rule with comment period at <http://www.cms.gov/physicianfeesched/PFS-Federal-Regulation-Notices.html>. The direct PE inputs are listed in a file called "CY 2015 PFS Direct PE Inputs," available on the CMS Web site under downloads for the CY 2015 PFS final rule with comment period at <http://www.cms.gov/physicianfeesched/PFS-Federal-Regulation-Notices.html>.

a. Finalizing CY 2014 Interim Final Work RVUs for CY 2015

(i) Refinement Panel

(1) Refinement Panel Process

As discussed in the 1993 PFS final rule with comment period (57 FR 55938), we adopted a refinement panel

process soon after implementing the fee schedule to assist us in reviewing the public comments on CPT codes with interim final work RVUs and in developing final work values for the subsequent year. We decided the panel would be comprised of a multispecialty group of physicians who would review and discuss the work involved in each procedure under review, and then each panel member would individually rate the work of the procedure. We believed a multispecialty group would balance the interests of the specialty societies who commented on the work RVUs with the budgetary and redistributive effects that could occur if we accepted extensive increases in work RVUs across a broad range of services. Depending on the number and range of codes that are subject to refinement in a given year, we establish refinement panels with representatives from four groups: Clinicians representing the specialty identified with the procedures in question; physicians with practices in related specialties; primary care physicians; and contractor medical directors (CMDs). Typical panels have included 8 to 10 physicians across the four groups.

Following the addition of section 1848(c)(2)(K) to the Act, which requires the Secretary periodically to review potentially misvalued codes and make appropriate adjustments to the RVUs, we reassessed the refinement panel process. As detailed in the CY 2011 PFS final rule with comment period (75 FR 73306), we believed that the refinement panel process might provide an opportunity to review and discuss the proposed and interim final work RVUs with a clinically diverse group of experts, who could provide informed recommendations following the discussion. Therefore, we indicated that we would continue the refinement process, but with administrative modification and clarification. We also noted that we would continue using the established panel composition that includes representatives from the four groups—clinicians representing the specialty identified with the procedures in question, physicians with practices in related specialties, primary care physicians, and CMDs.

At that time, we made a change in how we calculated refinement panel results. The basis of the refinement panel process is that, following discussion of the information but without an attempt to reach a consensus, each member of the panel submits an independent rating to CMS. Historically, the refinement panel's recommendation to change a work value or to retain the interim final value had

hinged solely on the outcome of a statistical test on the ratings (an F-test of panel ratings among the groups of participants). Over time, we found the statistical test used to evaluate the RVU ratings of individual panel members became less reliable as the physicians in each group tended to select a previously discussed value, rather than developing a unique value, thereby reducing the observed variability needed to conduct a robust statistical test. In addition, reliance on values developed using the F-test also occasionally resulted in rank order anomalies among services (that is, a more complex procedure is assigned lower RVUs than a less complex procedure). As a result, we eliminated the use of the statistical F-test and replaced it with the median work value of the individual panel members' ratings. We stated that this approach would simplify the refinement process administratively, while providing a result that reflects the summary opinion of the panel members based on a commonly used measure of central tendency that is not significantly affected by outlier values. We also clarified that we have the final authority to set the work RVUs, including making adjustments to the work RVUs resulting from the refinement process, and that we will make such adjustments if warranted by policy concerns (75 FR 73307).

We remind readers that the refinement panels are not intended to review the work RVUs for every code for which we did not accept the RUC-recommended work RVUs. Rather, refinement panels are designed for situations where there is new clinical information available that might provide a reason for a change in work values and where a multispecialty panel of physicians might provide input that would assist us in establishing work RVUs. To facilitate the selection of services for the refinement panels, commenters seeking consideration by a

refinement panel should specifically state in their public comments that they are requesting refinement panel review. Furthermore, we have asked commenters requesting refinement panel review to submit any new clinical information concerning the work required to furnish a service so that we can consider whether the new information warrants referral to the refinement panel (57 FR 55917).

We note that most of the information presented during the last several refinement panel discussions has been duplicative of the information provided to the RUC during its development of recommendations and considered by CMS in establishing values. As detailed above, we consider information and recommendations from the RUC when assigning proposed and interim final RVUs to services. Thus, if the only information that a commenter has to present is information already considered by the RUC, referral to a refinement panel is not appropriate. We request that commenters seeking refinement panel review of work RVUs submit supporting information that has not already been considered by the RUC in developing recommendations or by CMS in assigning proposed and interim final work RVUs. We can make best use of our resources, as well as those of the specialties and physician volunteers involved, by avoiding duplicative consideration of information by the RUC, CMS, and a refinement panel. To achieve this goal, CMS will continue to critically evaluate the need to refer codes to refinement panels in future years, specifically considering any new information provided by commenters.

(2) CY 2014 Interim Final Work RVUs Considered by the Refinement Panel

We referred to the CY 2014 refinement panel 19 CPT codes with CY 2014 interim final work values for which we received a request for refinement that met the requirements described above. For these 19 CPT

codes, all commenters requested increased work RVUs. For ease of discussion, we will be referring to these services as "refinement codes." Consistent with the process described above, we convened a multi-specialty panel of physicians to assist us in the review of the information submitted to support increased work RVUs. The panel was moderated by our physician advisors, and consisted of the following voting members:

- One to two clinicians representing the commenting organization.
- One to two primary care clinicians nominated by the American Academy of Family Physicians and the American College of Physicians.
- Four Contractor Medical Directors (CMDs).
- One to two clinicians with practices in related specialties, who were expected to have knowledge of the services under review.

The panel process was designed to capture each participant's independent judgment and his or her clinical experience which informed and drove the discussion of the refinement code during the refinement panel proceedings. Following the discussion, each voting participant rated the work of the refinement code(s) and submitted those ratings to CMS directly and confidentially. We note that not all voting participants voted for every CPT code. There was no attempt to achieve consensus among the panel members. As finalized in the CY 2011 PFS final rule with comment period (75 FR 73307), we calculated the median value for each service based upon the individual ratings that were submitted to CMS by panel participants.

Table 14 presents information on the work RVUs for the refinement codes, including the refinement panel ratings and the final CY 2015 work RVUs. In section II.G.2.a.ii., we discuss the CY 2015 work RVUs assigned each of the individual refinement codes.

TABLE 14—CODES REVIEWED BY THE 2014 MULTI-SPECIALTY REFINEMENT PANEL

HCPCS Code	Descriptor	CY 2014 interim final work RVU	RUC recommended work RVU	Refinement panel median rating	CY 2015 work RVU
19081	Biopsy of breast accessed through the skin with stereotactic guidance.	3.29	3.29	3.40	3.29
19082	Biopsy of breast accessed through the skin with stereotactic guidance.	1.65	1.65	1.78	1.65
19083	Biopsy of breast accessed through the skin with ultrasound guidance.	3.10	3.10	3.10	3.10
19084	Biopsy of breast accessed through the skin with ultrasound guidance.	1.55	1.55	1.55	1.55
19085	Biopsy of breast accessed through the skin with MRI guidance.	3.64	3.64	3.64	3.64
19086	Biopsy of breast accessed through the skin with MRI guidance.	1.82	1.82	1.82	1.82

TABLE 14—CODES REVIEWED BY THE 2014 MULTI-SPECIALTY REFINEMENT PANEL—Continued

HCPCS Code	Descriptor	CY 2014 interim final work RVU	RUC recommended work RVU	Refinement panel median rating	CY 2015 work RVU
19281	Placement of breast localization devices accessed through the skin with mammographic guidance.	2.00	2.00	2.00	2.00
19282	Placement of breast localization devices accessed through the skin with mammographic guidance.	1.00	1.00	1.00	1.00
19283	Placement of breast localization devices accessed through the skin with stereotactic guidance.	2.00	2.00	2.00	2.00
19284	Placement of breast localization devices accessed through the skin with stereotactic guidance.	1.00	1.00	1.00	1.00
19285	Placement of breast localization devices accessed through the skin with ultrasound guidance.	1.70	1.70	1.70	1.70
19286	Placement of breast localization devices accessed through the skin with ultrasound guidance.	0.85	0.85	0.85	0.85
19287	Placement of breast localization devices accessed through the skin with MRI guidance.	2.55	3.02	3.02	2.55
19288	Placement of breast localization devices accessed through the skin with MRI guidance.	1.28	1.51	1.51	1.28
43204	Injection of dilated esophageal veins using an endoscope	2.40	2.89	2.77	2.40
43205	Tying of esophageal veins using an endoscope	2.51	3.00	2.88	2.51
43213	Dilation of esophagus using an endoscope	4.73	5.00	5.00	4.73
43233	Balloon dilation of esophagus, stomach, and/or upper small bowel using an endoscope.	4.05	4.45	4.26	4.26
43255	Control of bleeding of esophagus, stomach, and/or upper small bowel using an endoscope.	3.66	4.20	4.20	3.66

(ii) Code-Specific Issues

For each code with an interim final work value, Table 15 lists the CY 2014 interim final work RVU and the CY 2015 work RVU and indicates whether we are finalizing the CY 2015 work RVU. For codes without a work RVU, the table includes a PFS procedure status indicator. A list of the PFS procedure status indicators can be found in Addendum A. If the CY 2015 Action column indicates that the CY

2015 values are interim final, we will accept public comments on these values during the public comment period for this final rule with comment period. A comprehensive list of all values for which public comments are being solicited is contained in Addendum C to the CY 2015 PFS final rule with comment period. A comprehensive list of all CY 2015 RVUs is in Addendum B to this final rule with comment period. All Addenda to PFS final rule are

available on the CMS Web site under downloads at <http://www.cms.gov/physicianfeesched/PFSFederalRegulationNotices.html/>. The time values for all codes are listed in a file called “CY 2015 PFS Work Time,” available on the CMS Web site under downloads for the CY 2015 PFS final rule with comment period at <http://www.cms.gov/physicianfeesched/downloads/>.

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TABLE 15: CY 2015 Actions on Codes with CY 2014 Interim Final RVUs

HCPCS Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
10030	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst), soft tissue (eg, extremity, abdominal wall, neck), percutaneous	3.00	3.00	Finalize
17000	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (eg, actinic keratoses); first lesion	0.61	0.61	Finalize
17003	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (eg, actinic keratoses); second through 14 lesions, each (list separately in addition to code for first lesion)	0.04	0.04	Finalize
17004	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (eg, actinic keratoses), 15 or more lesions	1.37	1.37	Finalize
17311	Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), head, neck, hands, feet, genitalia, or any location with surgery directly involving muscle, cartilage, bone, tendon, major nerves, or vessels; first stage, up to 5 tissue blocks	6.20	6.20	Finalize
17312	Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), head, neck, hands, feet, genitalia, or any location with surgery directly involving muscle, cartilage, bone, tendon, major nerves, or vessels; each additional stage after the first stage, up to 5 tissue blocks (list separately in addition to code for primary procedure)	3.30	3.30	Finalize
17313	Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), of the trunk, arms, or legs; first stage, up to 5 tissue blocks	5.56	5.56	Finalize

HCPCS Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
17314	Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), of the trunk, arms, or legs; each additional stage after the first stage, up to 5 tissue blocks (list separately in addition to code for primary procedure)	3.06	3.06	Finalize
17315	Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), each additional block after the first 5 tissue blocks, any stage (list separately in addition to code for primary procedure)	0.87	0.87	Finalize
19081	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including stereotactic guidance	3.29	3.29	Finalize
19082	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including stereotactic guidance (list separately in addition to code for primary procedure)	1.65	1.65	Finalize
19083	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including ultrasound guidance	3.10	3.10	Finalize
19084	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including ultrasound guidance (list separately in addition to code for primary procedure)	1.55	1.55	Finalize
19085	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including magnetic resonance guidance	3.64	3.64	Finalize
19086	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including magnetic resonance guidance (list separately in addition to code for primary procedure)	1.82	1.82	Finalize

HCPCS Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
19281	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including mammographic guidance	2.00	2.00	Finalize
19282	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including mammographic guidance (list separately in addition to code for primary procedure)	1.00	1.00	Finalize
19283	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including stereotactic guidance	2.00	2.00	Finalize
19284	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including stereotactic guidance (list separately in addition to code for primary procedure)	1.00	1.00	Finalize
19285	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including ultrasound guidance	1.70	1.70	Finalize
19286	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including ultrasound guidance (list separately in addition to code for primary procedure)	0.85	0.85	Finalize
19287	Placement of breast localization device(s) (eg clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including magnetic resonance guidance	2.55	2.55	Finalize
19288	Placement of breast localization device(s) (eg clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including magnetic resonance guidance (list separately in addition to code for primary procedure)	1.28	1.28	Finalize
23333	Removal of foreign body, shoulder; deep (subfascial or intramuscular)	6.00	6.00	Finalize
23334	Removal of prosthesis, includes debridement and synovectomy when performed; humeral or glenoid component	15.50	15.50	Finalize
23335	Removal of prosthesis, includes debridement and synovectomy when performed; humeral and glenoid components (eg, total shoulder)	19.00	19.00	Finalize
23600	Closed treatment of proximal humeral (surgical or anatomical neck) fracture; without manipulation	3.00	3.00	Finalize

HCPCS Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
24160	Removal of prosthesis, includes debridement and synovectomy when performed; humeral and ulnar components	18.63	18.63	Finalize
24164	Removal of prosthesis, includes debridement and synovectomy when performed; radial head	10.00	10.00	Finalize
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft	20.72	20.72	Finalize
27236	Open treatment of femoral fracture, proximal end, neck, internal fixation or prosthetic replacement	17.61	17.61	Finalize
27446	Arthroplasty, knee, condyle and plateau; medial or lateral compartment	17.48	17.48	Finalize
27447	Arthroplasty, knee, condyle and plateau; medial and lateral compartments with or without patella resurfacing (total knee arthroplasty)	20.72	20.72	Finalize
28470	Closed treatment of metatarsal fracture; without manipulation, each	2.03	2.03	Finalize
29075	Application, cast; elbow to finger (short arm)	0.77	0.77	Finalize
29581	Application of multi-layer compression system; leg (below knee), including ankle and foot	0.25	0.25	Finalize
29582	Application of multi-layer compression system; thigh and leg, including ankle and foot, when performed	0.35	0.35	Finalize
29583	Application of multi-layer compression system; upper arm and forearm	0.25	0.25	Finalize
29584	Application of multi-layer compression system; upper arm, forearm, hand, and fingers	0.35	0.35	Finalize
29824	Arthroscopy, shoulder, surgical; distal claviclectomy including distal articular surface (mumford procedure)	8.98	8.98	Finalize
29826	Arthroscopy, shoulder, surgical; decompression of subacromial space with partial acromioplasty, with coracoacromial ligament (ie, arch) release, when performed (list separately in addition to code for primary procedure)	3.00	3.00	Finalize
31237	Nasal/sinus endoscopy, surgical; with biopsy, polypectomy or debridement (separate procedure)	2.60	2.60	Finalize
31238	Nasal/sinus endoscopy, surgical; with control of nasal hemorrhage	2.74	2.74	Finalize
31239	Nasal/sinus endoscopy, surgical; with dacryocystorhinostomy	9.04	9.04	Finalize
31240	Nasal/sinus endoscopy, surgical; with concha bullosa resection	2.61	2.61	Finalize
33282	Implantation of patient-activated cardiac event recorder	3.50	3.50	Finalize

HCPCS Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
33284	Removal of an implantable, patient-activated cardiac event recorder	3.00	3.00	Finalize
33366	Transcatheter aortic valve replacement (tavr/tavi) with prosthetic valve; transapical exposure (eg, left thoracotomy)	35.88	35.88	Finalize
34841	Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including one visceral artery endoprosthesis (superior mesenteric, celiac or renal artery)	C	C	Finalize
34842	Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])	C	C	Finalize
34843	Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])	C	C	Finalize
34844	Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])	C	C	Finalize
34845	Endovascular repair of visceral aorta and infrarenal abdominal aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including one visceral artery endoprosthesis (superior mesenteric, celiac or renal artery)	C	C	Finalize

HCPCS Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
34846	Endovascular repair of visceral aorta and infrarenal abdominal aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])	C	C	Finalize
34847	Endovascular repair of visceral aorta and infrarenal abdominal aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])	C	C	Finalize
34848	Endovascular repair of visceral aorta and infrarenal abdominal aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])	C	C	Finalize
35301	Thromboendarterectomy, including patch graft, if performed; carotid, vertebral, subclavian, by neck incision	21.16	21.16	Finalize
36245	Selective catheter placement, arterial system; each first order abdominal, pelvic, or lower extremity artery branch, within a vascular family	4.90	4.90	Finalize
37217	Transcatheter placement of intravascular stent(s), intrathoracic common carotid artery or innominate artery by retrograde treatment, open ipsilateral cervical carotid artery exposure, including angioplasty, when performed, and radiological supervision and interpretation	20.38	20.38	Finalize
37236	Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; initial artery	9.00	9.00	Finalize

HCPCS Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
37237	Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; each additional artery (list separately in addition to code for primary procedure)	4.25	4.25	Finalize
37238	Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein	6.29	6.29	Finalize
37239	Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; each additional vein (list separately in addition to code for primary procedure)	2.97	2.97	Finalize
37241	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (eg, congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles)	9.00	9.00	Finalize
37242	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (eg, congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms)	10.05	10.05	Finalize
37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction	11.99	11.99	Finalize
37244	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation	14.00	14.00	Finalize
43191	Esophagoscopy, rigid, transoral; diagnostic, including collection of specimen(s) by brushing or washing when performed (separate procedure)	2.00	2.49	Finalize
43192	Esophagoscopy, rigid, transoral; with directed submucosal injection(s), any substance	2.45	2.79	Finalize

HCPSC Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
43193	Esophagoscopy, rigid, transoral; with biopsy, single or multiple	3.00	2.79	Finalize
43194	Esophagoscopy, rigid, transoral; with removal of foreign body(s)	3.00	3.51	Finalize
43195	Esophagoscopy, rigid, transoral; with balloon dilation (less than 30 mm diameter)	3.00	3.07	Finalize
43196	Esophagoscopy, rigid, transoral; with insertion of guide wire followed by dilation over guide wire	3.30	3.31	Finalize
43197	Esophagoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	1.48	1.52	Finalize
43198	Esophagoscopy, flexible, transnasal; with biopsy, single or multiple	1.78	1.82	Finalize
43200	Esophagoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	1.50	1.52	Finalize
43201	Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance	1.80	1.82	Finalize
43202	Esophagoscopy, flexible, transoral; with biopsy, single or multiple	1.80	1.82	Finalize
43204	Esophagoscopy, flexible, transoral; with injection sclerosis of esophageal varices	2.40	2.43	Finalize
43205	Esophagoscopy, flexible, transoral; with band ligation of esophageal varices	2.51	2.54	Finalize
43206	Esophagoscopy, flexible, transoral; with optical endomicroscopy	2.39	2.39	Finalize
43211	Esophagoscopy, flexible, transoral; with endoscopic mucosal resection	4.21	4.30	Finalize
43212	Esophagoscopy, flexible, transoral; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed)	3.38	3.50	Finalize
43213	Esophagoscopy, flexible, transoral; with dilation of esophagus, by balloon or dilator, retrograde (includes fluoroscopic guidance, when performed)	4.73	4.73	Finalize
43214	Esophagoscopy, flexible, transoral; with dilation of esophagus with balloon (30 mm diameter or larger) (includes fluoroscopic guidance, when performed)	3.38	3.50	Finalize
43215	Esophagoscopy, flexible, transoral; with removal of foreign body(s)	2.51	2.54	Finalize
43216	Esophagoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps	2.40	2.40	Finalize
43217	Esophagoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	2.90	2.90	Finalize

HCPCS Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
43220	Esophagoscopy, flexible, transoral; with transendoscopic balloon dilation (less than 30 mm diameter)	2.10	2.10	Finalize
43226	Esophagoscopy, flexible, transoral; with insertion of guide wire followed by passage of dilator(s) over guide wire	2.34	2.34	Finalize
43227	Esophagoscopy, flexible, transoral; with control of bleeding, any method	2.99	2.99	Finalize
43229	Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)	3.54	3.59	Finalize
43231	Esophagoscopy, flexible, transoral; with endoscopic ultrasound examination	2.90	2.90	Finalize
43232	Esophagoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s)	3.54	3.59	Finalize
43233	Esophagogastroduodenoscopy, flexible, transoral; with dilation of esophagus with balloon (30 mm diameter or larger) (includes fluoroscopic guidance, when performed)	4.05	4.17	Finalize
43235	Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	2.17	2.19	Finalize
43236	Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance	2.47	2.49	Finalize
43237	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures	3.57	3.57	Finalize
43238	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures)	4.11	4.26	Finalize
43239	Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple	2.47	2.49	Finalize
43240	Esophagogastroduodenoscopy, flexible, transoral; with transmural drainage of pseudocyst (includes placement of transmural drainage catheter[s]/stent[s], when performed, and endoscopic ultrasound, when performed)	7.25	7.25	Finalize
43241	Esophagogastroduodenoscopy, flexible, transoral; with insertion of intraluminal tube or catheter	2.59	2.59	Finalize

HCPCS Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
43242	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)	4.68	4.83	Finalize
43243	Esophagogastroduodenoscopy, flexible, transoral; with injection sclerosis of esophageal/gastric varices	4.37	4.37	Finalize
43244	Esophagogastroduodenoscopy, flexible, transoral; with band ligation of esophageal/gastric varices	4.50	4.50	Finalize
43245	Esophagogastroduodenoscopy, flexible, transoral; with dilation of gastric/duodenal stricture(s) (eg, balloon, bougie)	3.18	3.18	Finalize
43246	Esophagogastroduodenoscopy, flexible, transoral; with directed placement of percutaneous gastrostomy tube	3.66	3.66	Finalize
43247	Esophagogastroduodenoscopy, flexible, transoral; with removal of foreign body(s)	3.18	3.21	Finalize
43248	Esophagogastroduodenoscopy, flexible, transoral; with insertion of guide wire followed by passage of dilator(s) through esophagus over guide wire	3.01	3.01	Finalize
43249	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic balloon dilation of esophagus (less than 30 mm diameter)	2.77	2.77	Finalize
43250	Esophagogastroduodenoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps	3.07	3.07	Finalize
43251	Esophagogastroduodenoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	3.57	3.57	Finalize
43252	Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy	3.06	3.06	Finalize
43253	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided transmural injection of diagnostic or therapeutic substance(s) (eg, anesthetic, neurolytic agent) or fiducial marker(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)	4.68	4.83	Finalize
43254	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic mucosal resection	4.88	4.97	Finalize
43255	Esophagogastroduodenoscopy, flexible, transoral; with control of bleeding, any method	3.66	3.66	Finalize

HCPCS Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
43257	Esophagogastroduodenoscopy, flexible, transoral; with delivery of thermal energy to the muscle of lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease	4.11	4.25	Finalize
43259	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination, including the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis	4.14	4.14	Finalize
43260	Endoscopic retrograde cholangiopancreatography (ercp); diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	5.95	5.95	Finalize
43261	Endoscopic retrograde cholangiopancreatography (ercp); with biopsy, single or multiple	6.25	6.25	Finalize
43262	Endoscopic retrograde cholangiopancreatography (ercp); with sphincterotomy/papillotomy	6.60	6.60	Finalize
43263	Endoscopic retrograde cholangiopancreatography (ercp); with pressure measurement of sphincter of oddi	6.60	6.60	Finalize
43264	Endoscopic retrograde cholangiopancreatography (ercp); with removal of calculi/debris from biliary/pancreatic duct(s)	6.73	6.73	Finalize
43265	Endoscopic retrograde cholangiopancreatography (ercp); with destruction of calculi, any method (eg, mechanical, electrohydraulic, lithotripsy)	8.03	8.03	Finalize
43266	Esophagogastroduodenoscopy, flexible, transoral; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed)	4.05	4.17	Finalize
43270	Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)	4.21	4.26	Finalize
43273	Endoscopic cannulation of papilla with direct visualization of pancreatic/common bile duct(s) (list separately in addition to code(s) for primary procedure)	2.24	2.24	Finalize
43274	Endoscopic retrograde cholangiopancreatography (ercp); with placement of endoscopic stent into biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy, when performed, each stent	8.48	8.58	Finalize
43275	Endoscopic retrograde cholangiopancreatography (ercp); with removal of foreign body(s) or stent(s) from biliary/pancreatic duct(s)	6.96	6.96	Finalize

HCPCS Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
43276	Endoscopic retrograde cholangiopancreatography (ercp); with removal and exchange of stent(s), biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy, when performed, each stent exchanged	8.84	8.94	Finalize
43277	Endoscopic retrograde cholangiopancreatography (ercp); with trans-endoscopic balloon dilation of biliary/pancreatic duct(s) or of ampulla (sphincteroplasty), including sphincterotomy, when performed, each duct	7.00	7.00	Finalize
43278	Endoscopic retrograde cholangiopancreatography (ercp); with ablation of tumor(s), polyp(s), or other lesion(s), including pre- and post-dilation and guide wire passage, when performed	7.99	8.02	Finalize
43450	Dilation of esophagus, by unguided sound or bougie, single or multiple passes	1.38	1.38	Finalize
43453	Dilation of esophagus, over guide wire	1.51	1.51	Finalize
49405	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); visceral (eg, kidney, liver, spleen, lung/mediastinum), percutaneous	4.25	4.25	Finalize
49406	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); peritoneal or retroperitoneal, percutaneous	4.25	4.25	Finalize
49407	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); peritoneal or retroperitoneal, transvaginal or transrectal	4.50	4.50	Finalize
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy	39.88	39.88	Finalize
52332	Cystourethroscopy, with insertion of indwelling ureteral stent (eg, gibbons or double-j type)	2.82	2.82	Finalize
52356	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy including insertion of indwelling ureteral stent (eg, gibbons or double-j type)	8.00	8.00	Finalize
62310	Injection(s), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; cervical or thoracic	1.18		See II.G.3.a
62311	Injection(s), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; lumbar or sacral (caudal)	1.17		See II.G.3.a

HCPSC Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
62318	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, includes contrast for localization when performed, epidural or subarachnoid; cervical or thoracic	1.54		See II.G.3.a
62319	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, includes contrast for localization when performed, epidural or subarachnoid; lumbar or sacral (caudal)	1.50		See II.G.3.a
63047	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; lumbar	15.37	15.37	Finalize
63048	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; each additional segment, cervical, thoracic, or lumbar (list separately in addition to code for primary procedure)	3.47	3.47	Finalize
64616	Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis)	1.53	1.53	Finalize
64617	Chemodenervation of muscle(s); larynx, unilateral, percutaneous (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed	1.90	1.90	Finalize
64642	Chemodenervation of one extremity; 1-4 muscle(s)	1.65	1.65	Finalize
64643	Chemodenervation of one extremity; each additional extremity, 1-4 muscle(s) (list separately in addition to code for primary procedure)	1.22	1.22	Finalize
64644	Chemodenervation of one extremity; 5 or more muscles	1.82	1.82	Finalize
64645	Chemodenervation of one extremity; each additional extremity, 5 or more muscles (list separately in addition to code for primary procedure)	1.39	1.39	Finalize
64646	Chemodenervation of trunk muscle(s); 1-5 muscle(s)	1.80	1.80	Finalize
64647	Chemodenervation of trunk muscle(s); 6 or more muscles	2.11	2.11	Finalize
66183	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach	13.20	13.20	Finalize
67914	Repair of ectropion; suture	3.75	3.75	Finalize
67915	Repair of ectropion; thermocauterization	2.03	2.03	Finalize

HCPCS Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
67916	Repair of ectropion; excision tarsal wedge	5.48	5.48	Finalize
67917	Repair of ectropion; extensive (eg, tarsal strip operations)	5.93	5.93	Finalize
67921	Repair of entropion; suture	3.47	3.47	Finalize
67922	Repair of entropion; thermocauterization	2.03	2.03	Finalize
67923	Repair of entropion; excision tarsal wedge	5.48	5.48	Finalize
67924	Repair of entropion; extensive (eg, tarsal strip or capsulopalpebral fascia repairs operation)	5.93	5.93	Finalize
69210	Removal impacted cerumen requiring instrumentation, unilateral	0.61	0.61	Finalize
70450	Computed tomography, head or brain; without contrast material	0.85	0.85	Finalize
70460	Computed tomography, head or brain; with contrast material(s)	1.13	1.13	Finalize
70551	Magnetic resonance (eg, proton) imaging, brain (including brain stem); without contrast material	1.48	1.48	Finalize
70552	Magnetic resonance (eg, proton) imaging, brain (including brain stem); with contrast material(s)	1.78	1.78	Finalize
70553	Magnetic resonance (eg, proton) imaging, brain (including brain stem); without contrast material, followed by contrast material(s) and further sequences	2.29	2.29	Finalize
72141	Magnetic resonance (eg, proton) imaging, spinal canal and contents, cervical; without contrast material	1.48	1.48	Finalize
72142	Magnetic resonance (eg, proton) imaging, spinal canal and contents, cervical; with contrast material(s)	1.78	1.78	Finalize
72146	Magnetic resonance (eg, proton) imaging, spinal canal and contents, thoracic; without contrast material	1.48	1.48	Finalize
72147	Magnetic resonance (eg, proton) imaging, spinal canal and contents, thoracic; with contrast material(s)	1.78	1.78	Finalize
72148	Magnetic resonance (eg, proton) imaging, spinal canal and contents, lumbar; without contrast material	1.48	1.48	Finalize
72149	Magnetic resonance (eg, proton) imaging, spinal canal and contents, lumbar; with contrast material(s)	1.78	1.78	Finalize
72156	Magnetic resonance (eg, proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; cervical	2.29	2.29	Finalize
72157	Magnetic resonance (eg, proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; thoracic	2.29	2.29	Finalize
72158	Magnetic resonance (eg, proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; lumbar	2.29	2.29	Finalize

HCPSC Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
72191	Computed tomographic angiography, pelvis, with contrast material(s), including noncontrast images, if performed, and image postprocessing	1.81	1.81	Finalize
75896-26	Transcatheter therapy, infusion, other than for thrombolysis, radiological supervision and interpretation	1.31	1.31	Finalize
75896-TC	Transcatheter therapy, infusion, other than for thrombolysis, radiological supervision and interpretation	C	C	Finalize
75898-26	Angiography through existing catheter for follow-up study for transcatheter therapy, embolization or infusion, other than for thrombolysis	1.65	1.65	Finalize
75898-TC	Angiography through existing catheter for follow-up study for transcatheter therapy, embolization or infusion, other than for thrombolysis	C	C	Finalize
77001	Fluoroscopic guidance for central venous access device placement, replacement (catheter only or complete), or removal (includes fluoroscopic guidance for vascular access and catheter manipulation, any necessary contrast injections through access site or catheter with related venography radiologic supervision and interpretation, and radiographic documentation of final catheter position) (list separately in addition to code for primary procedure)	0.38	0.38	Finalize
77002	Fluoroscopic guidance for needle placement (eg, biopsy, aspiration, injection, localization device)	0.54	0.54	Finalize
77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinal diagnostic or therapeutic injection procedures (epidural or subarachnoid)	0.60	0.60	Finalize
77280	Therapeutic radiology simulation-aided field setting; simple	0.70	0.70	Finalize
77285	Therapeutic radiology simulation-aided field setting; intermediate	1.05	1.05	Finalize
77290	Therapeutic radiology simulation-aided field setting; complex	1.56	1.56	Finalize
77293	Respiratory motion management simulation (list separately in addition to code for primary procedure)	2.00	2.00	Finalize
77295	3-dimensional radiotherapy plan, including dose-volume histograms	4.29	4.29	Finalize
81161	Dmd (dystrophin) (eg, duchenne/becker muscular dystrophy) deletion analysis, and duplication analysis, if performed	X	X	Finalize
88112	Cytopathology, selective cellular enhancement technique with interpretation (eg, liquid based slide preparation method), except cervical or vaginal	0.56	0.56	Finalize
88120	Cytopathology, in situ hybridization (eg, fish), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen; manual	1.20	1.20	Finalize

HCPCS Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
88121	Cytopathology, in situ hybridization (eg, fish), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen; using computer-assisted technology	1.00	1.00	Finalize
88342	Immunohistochemistry or immunocytochemistry, per specimen; initial single antibody stain procedure	I		See II.G.3.b
88343	Immunohistochemistry or immunocytochemistry, each separately identifiable antibody per block, cytologic preparation, or hematologic smear; each additional separately identifiable antibody per slide (list separately in addition to code for primary procedure)	I		See II.G.3.b
88365	In situ hybridization (eg, fish), per specimen; initial single probe stain procedure	1.20		See II.G.3.b
88367	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; initial single probe stain procedure	1.30		See II. G.3.b
88368	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; initial single probe stain procedure	1.40		See II.G3.b
88375	Optical endomicroscopic image(s), interpretation and report, real-time or referred, each endoscopic session	I	0.91	Finalize
90785	Interactive complexity (list separately in addition to the code for primary procedure)	0.33	0.33	Finalize
90791	Psychiatric diagnostic evaluation	3.00	3.00	Finalize
90792	Psychiatric diagnostic evaluation with medical services	3.25	3.25	Finalize
90832	Psychotherapy, 30 minutes with patient and/or family member	1.50	1.50	Finalize
90833	Psychotherapy, 30 minutes with patient and/or family member when performed with an evaluation and management service (list separately in addition to the code for primary procedure)	1.50	1.50	Finalize
90834	Psychotherapy, 45 minutes with patient and/or family member	2.00	2.00	Finalize
90836	Psychotherapy, 45 minutes with patient and/or family member when performed with an evaluation and management service (list separately in addition to the code for primary procedure)	1.90	1.90	Finalize
90837	Psychotherapy, 60 minutes with patient and/or family member	3.00	3.00	Finalize
90838	Psychotherapy, 60 minutes with patient and/or family member when performed with an evaluation and management service (list separately in addition to the code for primary procedure)	2.50	2.50	Finalize
90839	Psychotherapy for crisis; first 60 minutes	3.13	3.13	Finalize

HCPCS Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
90840	Psychotherapy for crisis; each additional 30 minutes (list separately in addition to code for primary service)	1.50	1.50	Finalize
90845	Psychoanalysis	2.10	2.10	Finalize
90846	Family psychotherapy (without the patient present)	2.40	2.40	Finalize
90847	Family psychotherapy (conjoint psychotherapy) (with patient present)	2.50	2.50	Finalize
90853	Group psychotherapy (other than of a multiple-family group)	0.59	0.59	Finalize
90863	Pharmacologic management, including prescription and review of medication, when performed with psychotherapy services (list separately in addition to the code for primary procedure)	I	I	Finalize
92521	Evaluation of speech fluency (eg, stuttering, cluttering)	1.75	1.75	Finalize
92522	Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria);	1.50	1.50	Finalize
92523	Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria); with evaluation of language comprehension and expression (eg, receptive and expressive language)	3.00	3.00	Finalize
92524	Behavioral and qualitative analysis of voice and resonance	1.50	1.50	Finalize
93000	Electrocardiogram, routine ecg with at least 12 leads; with interpretation and report	0.17	0.17	Finalize
93010	Electrocardiogram, routine ecg with at least 12 leads; interpretation and report only	0.17	0.17	Finalize
93582	Percutaneous transcatheter closure of patent ductus arteriosus	12.56	12.56	Finalize
93583	Percutaneous transcatheter septal reduction therapy (eg, alcohol septal ablation) including temporary pacemaker insertion when performed	14.00	14.00	Finalize
93880	Duplex scan of extracranial arteries; complete bilateral study	0.60		See II.G.3.b
93882	Duplex scan of extracranial arteries; unilateral or limited study	0.40		See II.G.3.b
95816	Electroencephalogram (eeg); including recording awake and drowsy	1.08	1.08	Finalize
95819	Electroencephalogram (eeg); including recording awake and asleep	1.08	1.08	Finalize
95822	Electroencephalogram (eeg); recording in coma or sleep only	1.08	1.08	Finalize
95928	Central motor evoked potential study (transcranial motor stimulation); upper limbs	1.50	1.50	Finalize
95929	Central motor evoked potential study (transcranial motor stimulation); lower limbs	1.50	1.50	Finalize

HCPCS Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	0.21	0.21	Finalize
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)	0.18	0.18	Finalize
96367	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (list separately in addition to code for primary procedure)	0.19	0.19	Finalize
96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (list separately in addition to code for primary procedure)	0.17	0.17	Finalize
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	0.28	0.28	Finalize
96415	Chemotherapy administration, intravenous infusion technique; each additional hour (list separately in addition to code for primary procedure)	0.19	0.19	Finalize
96417	Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour (list separately in addition to code for primary procedure)	0.21	0.21	Finalize
97610	Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day	C	C	Finalize
98940	Chiropractic manipulative treatment (cmt); spinal, 1-2 regions	0.46	0.46	Finalize
98941	Chiropractic manipulative treatment (cmt); spinal, 3-4 regions	0.71	0.71	Finalize
98942	Chiropractic manipulative treatment (cmt); spinal, 5 regions	0.96	0.96	Finalize
99446	Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 5-10 minutes of medical consultative discussion and review	B	B	Finalize
99447	Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 11-20 minutes of medical consultative discussion and review	B	B	Finalize
99448	Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 21-30 minutes of medical consultative discussion and review	B	B	Finalize

HCPSC Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
99449	Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 31 minutes or more of medical consultative discussion and review	B	B	Finalize
99481	Reduce temperature of total body in a critically ill neonate, per day	C		Deleted
99482	Reduce temperature of head in a critically ill neonate, per day	C		Deleted
G0461	Immunohistochemistry or immunocytochemistry, per specimen; first single or multiplex antibody stain	0.60		Deleted
G0462	Immunohistochemistry or immunocytochemistry, per specimen; each additional single or multiplex antibody stain (list separately in addition to code for primary procedure)	0.24		Deleted

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In the following section, we discuss each code for which we received a comment on the CY 2014 interim final work value or work time during the comment period for the CY 2014 final rule with comment period or for which we are modifying the CY 2014 interim final work RVU, work time or procedure status indicator for CY 2015. If a code in Table 15 is not discussed in this section, we did not receive any comments on that code and are finalizing the interim final work RVU and time without modification for CY 2015.

(1) Mohs Surgery (CPT Codes 17311 and 17313)

As detailed in the CY 2014 PFS final rule with comment period, we maintained the CY 2013 work RVUs for CPT codes 17311 and 17313 codes, based upon the RUC-recommended work RVUs.

Comment: We received a comment that was supportive of the interim final work RVU.

Response: We thank the commenter for their support and are finalizing the CY 2014 interim final values for CY 2015.

(2) Breast Biopsy (CPT Codes 19081, 19082, 19083, 19084, 19085, 19086, 19281, 19282, 19283, 19284, 19285, 19286, 19287, and 19288)

For CY 2014, the CPT Editorial Panel created 14 new codes, CPT codes 19081 through 19288, to describe breast biopsy and placement of breast localization

devices, and the RUC recommended work RVUs for each of these codes. In the 2014 final rule with comment period, we established interim final values for all of these codes as recommended by the RUC except for CPT code 19287 and its add-on CPT code, 19288, which are used for magnetic resonance (MR) guidance. We expressed concern that for CPT code 19287 the RUC-recommended work RVUs were too high in relation to those of other marker placement codes, and refined it to a lower value. Since we had adopted the RUC recommendation that all the add-on codes in this family have work RVUs equal to 50 percent of the base code's work RVU, our refinement of CPT code 19287 resulted in a refinement of CPT code 19288 also. We also changed the intraservice time of CPT code 19286, an add-on code, from 19 minutes to 15 minutes since we believed the intraservice time of an add-on code should not be higher than its base code and the base code for CPT code 19286, has an intraservice time of 15 minutes.

Comment: Several commenters disagreed with the new CPT coding structure for breast biopsy and placement of breast localization devices because, unlike the predecessor structure, it fails to distinguish between the two types of biopsy devices—standard core needle and vacuum assisted. One commenter suggested that the payment should be higher when services are vacuum assisted, and suggested that CMS create a modifier to report when these services are furnished

using a vacuum assisted biopsy or create a series of G-codes that distinguish between standard core needle biopsy and vacuum assisted biopsy.

Response: We prefer to use the CPT coding structure unless a programmatic need suggests that an alternative coding structure is preferable. In this case, we believe that we can pay appropriately for these services using the new CPT coding structure. To the extent that the commenters think the CPT coding system is not ideal for these services, we believe the CPT Editorial Panel is the appropriate forum for this concern. The commenters are mistaken regarding how the inputs for these codes were determined as they are based upon the typical service being vacuum assisted.

Comment: Several commenters disagreed with the interim final work RVUs we established for CPT codes 19287 and 19288, stating that the higher RUC-recommended RVUs were more appropriate and would maintain relativity within the family. The commenters stated that these services have longer intraservice time than other codes in the marker placement family, are of high intensity, produce high patient and family anxiety, and have higher malpractice costs. One commenter requested that the entire breast biopsy code family be referred to refinement. Other commenters requested refinement panel review of selected codes within this family.

Response: Based upon this request, we referred this family of codes to the CY 2014 multi-specialty refinement panel for further review. Prior to CY

2014, breast biopsies and marker placements were billed using a single code. In addition, the appropriate image guidance code was separately billed. Prior to CY 2014, there were individual guidance codes for the different types of guidance including MR and stereotactic guidance.

For CY 2013, the MR guidance code, CPT code 77032, had a lower work RVU than the stereotactic guidance code, CPT code 77031. Combining the values for the marker placement or biopsy codes with the guidance codes should not, in our view, result in a change in the rank order of the guidance. Accordingly, we do not believe the bundled code that includes MR guidance should now be valued significantly higher than one that includes the stereotactic guidance. Also, the refinement panel discussions did not provide new clinical information. Therefore, we continue to believe the CY 2014 interim final values are appropriate for CPT codes 19287 and 19288, and are finalizing them for CY 2015.

Comment: Commenters stated that the RUC-recommended intraservice time of 19 minutes for CPT code 19286, which is an add-on code, was incorrect and that the code should have the same intraservice time as its base code (15 minutes) rather than the 14 minutes assigned by CMS. The commenter said that this was consistent with the other base code/add-on relationships across the family.

Response: We agree and are finalizing the intraservice time for CPT code 19286 at 15 minutes.

Comment: In response to our request for confirmation that a post procedure mammogram is typically furnished with a breast marker placement procedure, commenters agreed that it was. However, they disagreed with our assertion that if it was typical it should be bundled with the appropriate breast marker procedures. Commenters said that it should be a separately reportable service because it requires additional work not captured by the codes in this family.

Response: We thank commenters for their feedback. We are not bundling post procedure mammograms with the appropriate breast marker codes at this time, but will consider whether as a services that typically occur together they should be bundled.

(3) Hip and Knee Replacement (CPT Codes 27130, 27446 and 27447)

In the CY 2014 final rule with comment period we established interim final values for three CPT codes for hip and knee replacements that had previously been identified as potentially

misvalued codes under the CMS high expenditure procedural code screen. For CY 2014, we established the RUC-recommended work value of 17.48 as interim final work RVUs for CPT code 27446. As we explained in the CY 2014 final rule with comment period, we established interim final work RVUs for CPT codes 27130 and 27447 that varied from those recommended by the RUC based upon information that we received from the relevant specialty societies. We noted that the information presented by the specialty societies and the RUC raised concerns regarding the appropriate valuation of these services, especially related to the use of the best data source for determining the intraservice time involved in furnishing PFS services. Specifically, there was significant variation between the time values estimated through a survey versus those collected through specialty databases. We characterized our concerns saying, “The divergent recommendations from the specialty societies and the RUC regarding the accuracy of the estimates of time for these services, including both the source of time estimates for the procedure itself as well as the inpatient and outpatient visits included in the global periods for these codes, lead us to take a cautious approach in valuing these services.”

With regard to the specific valuations, we agreed with the RUC’s recommendation to value CPT codes 27130 and 27447 equally. We explained that we modified the RUC-recommended work RVUs for these two codes to reflect the visits in the global period as recommended by the specialty societies, resulting in a 1.12 work RVU increase from the RUC-recommended value for each code. Accordingly, we assigned CPT codes 27130 and 27447 an interim final work RVU of 20.72. We sought public comment regarding, not only the appropriate work RVUs for these services, but also the most appropriate reconciliation for the conflicting information regarding time values for these services as presented to us by the physician community. We also sought public comment on the use of specialty databases as compared to surveys for determining time values, potential sources of objective data regarding procedure times, and levels of visits furnished during the global periods for the services described by these codes.

Comment: The RUC submitted comments explaining how it reached its recommendations for these codes and that it followed its process consistently in developing its recommendations on these codes. All those who commented specifically on the interim final work

RVUs for these codes objected to the interim final work RVUs—some citing potential access problems. Commenters suggested that we use more reliable time data. Commenters suggested that valuation should be based on actual time data, which demonstrates that the time for this code has not changed since the last valuation; and thus the work RVUs should not decrease from the CY 2013 values. Among the commenters’ suggestions were using data from the Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement (FORCE-TJR), which includes data on more than 15,000 total lower extremity joint arthroplasty procedures, including time in/time out data for at least half of the procedures, and working with the specialty societies to explore the best data collection methods. A commenter suggested restoring the CY 2013 work RVUs until additional time data are available. Another commenter suggested valuing these services utilizing a reverse building block methodology resulting in work RVU of 21.18 for CPT codes 27130 and 22.11 for CPT code 27447. A commenter stated that the hip and knee replacement codes should be valued differently since they are clinically different procedures. Two commenters expressed concern regarding the use of a final rule to establish interim values for established hip and knee procedures due to the lack of opportunity it provides stakeholders to analyze and comment on reductions prior to implementation.

Response: In the CY 2014 final rule with comment period, we noted concerns about the time data used in valuing these services and requested additional input from stakeholders regarding using other sources of data beyond the surveys typically used by the RUC. We do not believe that we received the kind of information and the level of detail about the other types of data suggested by commenters that we would need to be able to use routinely in valuing procedures. We will continue to explore the use of other data on time. As we discuss in section II.B. we have engaged contractors to assist us in exploring alternative data sources to use in determining the times associated with particular services. At this time, we are not convinced that data from another source would result in an improved value for these services. Nor did we find the reasons given for modifying the interim final work values established in CY 2014. The interim final values are based upon the best data we have available and preserve appropriate relativity with other codes.

Accordingly, we are finalizing the interim final values for these procedures.

(4) Transcatheter Placement Intravascular Stent (CPT Code 37236, 37237, 37238, and 37239)

For CY 2014, we established the RUC-recommended work RVUs for newly created CPT codes 37236, 37237, and 37238 as the interim final values. We disagreed with the RUC-recommended work RVU for CPT code 37239, which is the add-on code to CPT code 37238, for the placement of an intravascular stent in each additional vein. As we described in the CY 2014 final rule with comment period we believe that the work for placement of an additional stent in a vein should bear the same relationship to the work of placing an initial stent in the vein as the placement of an additional stent in an artery to the placement of the initial stent in an artery.

Comment: Many commenters indicated that our valuation of CPT code 37239 was inappropriate. They indicated that instead we should use the RUC's recommended work RVU of 3.34 for this code since the procedure is more intense and requires more physician work than would result from the comparison made by CMS. One commenter requested that CPT code 37239 be referred to the refinement panel.

Response: After re-review, we continue to believe that the ratio of the work of the placement of the initial stent to the placement of additional stents is the same whether the stents are placed in an artery or a vein, and accordingly the appropriate ratio is found in the RUC-recommended work RVUs of CPT codes 37236 and 37237, the comparable codes for the arteries. For that reason, we are finalizing our CY 2014 interim final values. Additionally, we did not refer these codes for refinement panel review because the criteria for refinement panel review were not met.

(5) Embolization and Occlusion Procedures (CPT Codes 37242 and 37243)

For CY 2014, we established interim final work RVUs for these two codes based upon the survey's 25th percentile. As we discussed in the CY 2014 interim final rule with comment period, we believed that the RUC-recommended work RVU for CPT code 37242 did not adequately take into account the substantial decrease in intraservice time. We indicated that we believed that the survey's 25th percentile work RVU of 10.05 was more consistent with the

decreases in intraservice time since its last valuation and more appropriately reflected the work of the procedure. Similarly, we did not believe that the RUC-recommended work RVU for CPT code 37243 adequately considered the substantial decrease in intraservice time for the procedure; and we also use the survey's 25th percentile for CPT code 37243.

Comment: Many commenters disagreed with our interim final valuation of 37242, including one who recommended a work RVU of 11.98. One commenter also believed the work RVU assigned to CPT code 37243 was inappropriate and recommended instead a work RVU of 14.00. Commenters requested that the family of codes be referred for refinement.

Response: After consideration of the comments, we continue to believe that work RVUs should reflect the decreases in intraservice time that have occurred since the last valuation. As a result, we continue to believe that our CY 2014 interim final values are most appropriate and are finalizing them for CY 2015. Additionally, we did not refer these codes for refinement panel review because the criteria for refinement panel review were not met.

(6) Rigid Transoral Esophagoscopy (CPT Codes 43191, 43192, 43193, 43194, 43195 and 43196)

We established CY 2014 interim final work RVUs for the rigid transoral esophagoscopy codes using a ratio of 1 RVU per 10 minutes of intraservice time, resulting in a RVU of 2.00 for CPT code 43191, 3.00 for CPT code 43193, 3.00 for CPT code 43194, 3.00 for CPT code 43195, and 3.30 for CPT code 43196. As we detailed in the CY 2014 final rule with comment period, the surveys showed that this ratio was reflected for about half of the rigid transoral esophagoscopy codes. Additionally, we noted that this ratio was further supported by the relationship between the CY 2013 work value of 1.59 RVUs for CPT code 43200 (Esophagoscopy, rigid or flexible; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure)) and its intraservice time of 15 minutes. For CPT code 43192, the 1 work RVU per 10 minutes ratio resulted in a value that was less than the survey low, and thus did not appear to be appropriate for this procedure. Therefore, we established a CY 2014 interim final work RVU for CPT code 43192 of 2.45 based upon the survey low.

Comment: Multiple commenters objected to the interim final work RVUs assigned to CPT codes 43191–43196,

and expressed dissatisfaction with CMS's explanation for the valuations. The commenters specifically noted that CMS did not account for the difference in intensity between flexible and rigid scopes now that there are separate codes for these procedures. The commenters also suggested that the reduction in time in the RUC recommendations for codes 43191, 43193, 43195, and 43196 was also based on data from procedures with flexible scopes. The commenters also stated that our valuation of services based upon 1 work RVU per 10 minutes of intraservice time was inappropriate and was based on the survey low, which is an anomalous outlier. The commenters suggested the following work RVUs based upon the RUC recommended values: 2.78 for CPT code 43191, 3.21 for CPT code 43192, 3.36 for CPT code 43193, 3.99 for CPT code 43194, 3.21 for CPT code 43195 and 3.36 for CPT code 43196. Finally, the commenters asked that all these codes be referred to a refinement panel for reconsideration.

Response: After consideration of the comments, we agree that modification of the CY 2014 interim final values is appropriate. Based upon the information provided in comments and further investigation, we believe that greater intensity is involved in furnishing rigid than flexible transoral esophagoscopy. Accordingly, rather than assigning 1 work RVU per 10 minutes of intraservice time as we did for the CY 2014 interim final, we are assigning a final work RVU to the base code, CPT code 43191, of 2.49. This work RVU is based on increasing the work RVU of the previous comparable code (1.59) to reflect the percentage increase in time for the CY 2014 code. For the remaining rigid esophagoscopy codes, we developed RVUs by starting with the RVUs for the corresponding flexible esophagoscopy codes, and increasing those values by adding the difference between the base flexible esophagoscopy and the base rigid esophagoscopy codes to arrive at final RVUs. We are establishing a final work RVU of 2.79 to CPT code 43192, 2.79 to CPT code 43193, 3.51 to CPT code 43194, 3.07 to CPT code 43195, and 3.31 to CPT code 43196. These codes were not referred to refinement because the request did not meet the criteria for referral.

(7) Flexible Transnasal Esophagoscopy (CPT Codes 43197 and 43198)

We established CY 2014 interim final work RVUs of 1.48 for CPT code 43197 and 1.78 for CPT code 43198. As detailed in the CY 2014 final rule with comment period, we removed 2 minutes

of the pre-scrub, dress and wait preservice time from the calculation of the work RVUs that we established for CY 2014 for CPT codes 43200 and 43202 because we believed that unlike the transoral codes, which they correspond to, the transnasal services are not typically furnished with moderate sedation.

Comment: Multiple commenters objected to the work RVUs for these codes and in particular to CMS basing its valuation on the fact that these codes typically do not involve moderate sedation. Although the commenters agreed that these codes typically do not involve moderate sedation, they said that procedures involving local/topical anesthesia often take more work than those involving general sedation due to the difficulties of furnishing services to a conscious and often anxious patient. Some also noted that it ignores the time necessary to apply local/topical anesthesia and wait for it to take effect. A commenter urged CMS to establish values based upon the RUC recommendations. Commenters requested that these codes be referred for refinement.

Response: After consideration of the comments, we agree that the work RVUs for these codes should not be reduced because moderate sedation is not typically used. Accordingly, we agree with the RUC recommendation to assign the same work RVUs to these codes as to CPT code 43200 (Esophagoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing when performed) and 43202 (Esophagoscopy, flexible, transoral; with biopsy, single or multiple) the comparable transoral codes. We are finalizing work RVUs of 1.52 and 1.82 for CPT codes 43197 and 43198, respectively. We did not refer these codes to refinement because the request did not meet the criteria for refinement panel review.

(8) Flexible Transoral Esophagoscopy, (CPT Codes 43200, 43202, 43204, 43205, 43211, 43212, 43213, 43214, 43215, 43227, 43229, 43231, and 43232)

We established CY 2014 interim final work RVUs for the flexible transoral esophagoscopy family, which are detailed in Table 15. As we described in the CY 2014 final rule with comment period, to establish work values for these codes we used a variety of methodologies as did the RUC. The methodologies used by CMS And the RUC include basing values on the surveys (either medians or 25th percentiles), crosswalking values to other codes, using the building block methodology, and valuing a family of

codes based on the incremental differences in the work RVUs between the codes being valued and another family of codes. As we did for the rigid transoral esophagoscopy codes, in addition to the methodologies used by the RUC, we also reduced the work RVUs for particular codes in direct proportion to the reduction in times that were recommended by the RUC. Using these methodologies, we assigned the RUC-recommended work RVUs for five codes in this family; for the other eight codes we used these same methodologies but because of different values for a base code or variation in the crosswalk selected we obtained different values.

Comment: Commenters objected to the interim final RVUs we assigned for CPT code 43200, the base code for flexible transoral esophagoscopy, because they did not believe the work RVU for the code should be less than they were as of CY 2013 when there was a single code to report both flexible and rigid esophagoscopy services. Commenters also disagreed with the way we used standard methodologies to value many of these codes, including using the ratio of 1 work RVU per 10 minutes of intraservice time to CPT code 43200. Commenters requested that we accept the RUC values for all the flexible transoral esophagoscopy codes and asked that we refer all these codes to the refinement panel.

Response: Although refinement was requested for all of the flexible transoral esophagoscopy codes, we found that the codes (CPT codes 43204, 43205 and 43233) met the refinement criteria, and those were referred to the refinement panel. After consideration of the comments and the refinement panel results, we are revising the work RVUs for many of the codes in this family.

For CPT code 43200, which is the base code for flexible transoral esophagoscopy, we agree with commenters that another methodology is preferable to applying the work RVU ratio of 1 RVU per 10 minutes of intraservice time. In revaluing this service, we subtracted 0.07 to account for the 3 minute decrease in postservice time since the last valuation from the CY 2013 work RVU for the predecessor base code, which resulted in a work RVU of 1.52. We are finalizing this work RVU.

The CY 2014 interim final work RVUs for CPT codes 43201, 43202, 43204, 43205 and 43215 were all based upon methodologies using the work RVU of the base code, 43200. As we are establishing a final value for CPT code 43200 that is higher than the CY 2014 interim final value, we are also

adjusting the work RVUs for the other codes based upon the new work RVU for CPT code 43200. We are finalizing a work RVU of 1.82 for 43201, 1.82 for 43202, 2.43 for 43204, 2.54 for 43205, and 2.54 for 43215.

CPT codes 43204 and 43205 were considered by the refinement panel. The refinement panel median for each of these codes was 2.77 and 2.88, respectively. The refinement panel discussion reiterated the information presented to the RUC and in the comments in response to the CY 2014 final rule with comment period, such as that the typical patient for these codes are sicker and thus the work is more intense. Because we do not agree with commenters' contention that higher work RVUs are warranted since these codes involve the sicker patients or that our methodology for calculating the interim final RVUs was inappropriate, we are establishing final values determined using these methodologies. However, due to the change in the base code, CPT code 43200, as discussed in the previous paragraph the final values for these codes are higher than the interim final values.

In the CY 2014 final rule with comment period, we assigned an interim final work RVU of 4.21 to CPT code 43211 by using a comparable esophagogastroduodenoscopy (EGD) code and subtracting the difference in work between the base esophagoscopy and base EGD codes. After consideration of the comments that indicated the interim final work RVU of 4.21 was too low, we believe this code should instead be crosswalked to CPT code 31636 (Bronchoscopy bronch stents), which we believe is a comparable service with comparable intensity. It has the same intraservice time and slightly higher total time. As a result we are finalizing a work RVU of 4.30.

As we noted in the CY 2014 final rule with comment period, we crosswalked the interim final work RVU for CPT 43212 to that of CPT code 43214. Since we are increasing the work RVU for CPT code 43214, we are also increasing the work RVU for CPT code 43212, which is consistent with comments that we had undervalued this procedure.

As we detailed in the CY 2014 final rule with comment period, we based the work RVU of 4.73 for CPT code 43213 on the value of CPT code 43220, increased proportionately to reflect the longer intraservice time of CPT code 43213. The refinement panel median was 5.00 for this code. No new information was presented at the refinement panel. We continue to believe that 4.73 is the appropriate work RVU and are finalizing it.

Based upon the information presented by commenters about the typical patient and the advanced skills required for the procedure, we are changing our method of valuing CPT code 43214. We believe it should be crosswalked to CPT 52214 (cystoscopy), which we believe is similar in intensity. This results in a final work RVU of 3.50 as compared to an interim final of 3.38. This refinement also supports the belief made by commenters that the work of CPT code 43214 is greater than the interim final work RVU. Therefore, we are finalizing a work RVU of 3.50 for CPT code 43214.

For CPT code 43227, we modified the CY 2013 work RVU to reflect the percentage decrease in intraservice time of 36 minutes to 30 minutes in the RUC recommendation to establish a CY 2014 interim final value of 2.99. The commenters stated that the survey validates the RUC recommendation of 3.26 and that the drop in intraservice time that upon which we based our change in the work RVU was inappropriate since the intraservice time had not really changed. They contend that the change was from moving the time for moderate sedation from intraservice to preservice. We disagree. We have no information from the RUC that leads us to believe that when the pre-service packages were developed several years ago and moderate sedation was explicitly recognized as a pre-service item that the RUC also intended CMS to assume that the intraservice times were no longer correct. We believe that our proposed valuation methodology is correct and thus are finalizing a work RUV of 2.99.

Commenters, disagreeing with our crosswalk of CPT code 43229 to CPT code 43232, stated that the two codes were not comparable. We disagree. We continue to believe this crosswalk is appropriate as the times and intensities are quite similar. We note that the RUC also bases crosswalks on the comparability of time and intensity of codes and not on the clinical similarity of work. Thus, we will continue this crosswalk. However, as discussed below, we are refining the interim final value of CPT code 43232 to 3.59 and thus are finalizing the work RVU of 3.59 for CPT code 43229.

For CPT code 43231, we added the work of an endobronchial ultrasound (EBUS) to the work of the base esophagoscopy code to arrive at our interim final value. The commenters disagreed with our approach, stating that the EBUS code is an add-on code and as such does not have pre- and postservice work. We agree that pre- and postservice work is not included in the EBUS code nor should it be for the

ultrasound portion of the examination of esophagus. Therefore, we are finalizing a work RVU of 2.90.

For CPT code 43232, the commenters stated our interim final value is too low and that the work involved in this code is appropriately reflected in the RUC recommendation. They objected to our basing the work RVU for 43232 on the difference between the RUC-recommended values for this code and CPT code 43231. We learned from the comments that the typical patient for this service has advanced cancer and agree that our interim final value may not represent the full extent of the work involved in this procedure. Therefore, we are crosswalking this code to CPT code 36595 (Mechanical removal of pericatheter obstructive material (eg, fibrin sheath) from central venous device via separate venous access), which has identical intraservice time, slightly less total time, and a slightly higher intensity and are finalizing a work RVU of 3.59.

(10) Esophagogastroduodenoscopy (EGD) (CPT Codes 43233, 43235, 43236, 43237, 43238, 43239, 43242, 43244, 43246, 43247, 43249, 43253, 43254, 43255, 43257, 43259, 43266, and 43270.

We established interim final work RVUs for various EGD codes in the CY 2014 final rule with comment period. In this section, we discuss the 18 EGD codes on which we received comments disagreeing with or making recommendations for changes in our interim final values. As we detailed in the CY 2014 final rule with comment period, we valued many of these codes by adding the additional work of an EGD to the comparable esophagoscopy (ESO) code. We determined the additional work of an EGD by subtracting the work RVU of CPT code 43200, the base ESO code, from the work of CPT code 43235, the base EGD code. For example, CPT code 43233 is an identical procedure to CPT code 43214 except that it uses EGD rather than ESO. We valued it by adding the additional work of EGD to the work RVU of CPT code 43214, resulting in an interim final work RVU of 4.05. We valued the additional work the same way the RUC did in its recommendations. The following EGD codes were valued in the same way using the code in parentheses as the corresponding ESO code: 43233 (43214), 43236 (43201), 43237 (43231), 43238 (43232), 43247 (43215), 43254 (43211), 43255 (43227), 43266 (43212), and 43270 (43229). In valuing CPT codes 43235, we agreed with the RUC recommended work RVU difference between this EGD base code and the

esophagoscopy base code, CPT 43200 but applied the difference to our CY 2014 RVU values. In a similar fashion, in valuing CPT code 43242 we agreed with the RUC recommended methodology of which took the increment between CPT code 43238 and CPT code 43237 but we applied the difference to our CY 2014 values. In order to value other EGD codes, we crosswalked the services to similar procedures; specifically for CY 2014 we crosswalked CPT codes 43239 to 43236, 43246 to 43255, 43253 to 43242 and 43257 to 43238. We valued CPT codes 43244 and 43249 through acceptance of the RUC work RVU recommendation. Lastly, we valued CPT code 43259 by adjusting the CY 2013 work RVU to account for the CY 2014 RUC recommended reduction in total time.

Comment: For all codes, commenters objected to our work RVUs and said that our reductions from the RUC recommendations were based on a decrease in intraservice time that did not reflect a change in the time required to furnish the procedures but rather only a change in which part of the procedure the RUC includes the moderate sedation time. Commenters disagree with our valuing CPT code 43233 based on the value of CPT code 43214, saying that CPT code 43233 is more intense due to the risk of perforation, and that the achalasia patients are at high risk and poor candidates for surgery. Commenters disagreed with our methodology for valuing CPT code 43235, and suggested that we use the RUC crosswalk to CPT code 31579, contending that the slight reductions in pre- and post-service times are consistent with the slight drop in the RUC-recommended RVU. For CPT code 43237, commenters also noted a rank order anomaly because the interim final work RVU for this code is the same as for CPT code 43251. Commenters said that the robust survey data on CPT code 43238 should override CMS decisions. With regard to CPT code 43239, commenters suggest that the survey is wrong and further point to the fact that our valuation results in the same value for CPT code 43239 as the base EGD code, which they state is not appropriate due to the additional work in CPT code 43239. Commenters disagreed with our value for CPT code 43242 stating that we inappropriately valued CPT code 43259, which we used in calculating the work RVUs for CPT code 43242. Commenters objected to our value of CPT code 43246 because they disagree with the work RVU for the code that it is crosswalked to, CPT code 43255. Commenters urged us to modify

our work RVU for CPT code 43247 to equal the RUC recommendation. For CPT code 43253, commenters did not disagree with the valuation approach, but disagreed with the valuation we had assigned to the base code, CPT code 43259, which affected the valuation of CPT code 43253. Comments indicated that they did not understand how the value of CPT code 43254 was derived. Commenters indicated that they disagreed with the reduction in the work in CPT code 43255 due to a decrease in time. They also cited that this was an emergency procedure in unstable patients and that it was more difficult to control bleeding in the stomach than in the esophagus. For CPT code 43257, commenters disagreed with our crosswalk to CPT code 43238 indicating that CPT code 43257 was more intense than CPT code 43238. Commenters acknowledged that reduced times should result in reduced work, but disagreed with our proportional reduction approach. Commenters agreed with our approach to valuing CPT code 43266, but disagreed with the valuation of the CPT code 43212, that we used as the base. With regard to CPT code 43270, commenters disagreed with using CPT code 43229 as the base.

Response: For each of these codes, commenters were concerned that we did not accept the RUC-recommended values. Their common reasoning for urging us to accept the RUC-recommended values was that moderate sedation time had been removed from intraservice time and that these intraservice time changes should not result in a change in the RUC-recommended RVU. However, for CPT codes 43233, 43236, 43237, 43238, 43247, 43254, 43255, 43266, and 43270, we used the standard methodology described above for valuing EGD codes and did not base our values on the time change. Thus, any refinements to the RUC recommendations for the EGD codes are solely due to refinements in the ESO codes. We discussed our valuations of these codes in the previous section. Since we have finalized most of the ESO codes at higher levels than the CY 2014 interim final values, we are making corresponding increases in the EGD codes. Therefore, we are finalizing these codes at the following work RVUs: 43233 at 4.17, 43235 at 2.19, 43236 at 2.49, 43237 at 3.57, 43238 at 4.26, 43247 at 3.21, 43254 at 4.97, 43255 at 3.66, 43266 at 4.17, and 43270 at 4.26.

CPT code 43233 was referred to the refinement panel and received a median work RVU of 4.26. As outlined above, we are finalizing a work RVU of 4.17 for

CPT code 43233 at 4.17, which is higher than our interim value of 4.05, but consistent with our valuation of the other EGD codes. We do not believe that the comments provided at the refinement panel justify adoption of the higher median value.

The interim final work value of CPT code 43239 was crosswalked to the work RVU of CPT code 43236. Since we increased the final work RVU from the interim final for this code, the final work RUV of CPT code 43239 increases to 2.49.

(11) Endoscopic Retrograde Cholangiopancreatography (ERCP) (CPT Codes 43263, 43274, 43276, 43277 and 43278)

In the CY 2014 final rule with comment period we established interim final work RVUs for several ERCP codes due to coding revisions. For all those codes not discussed in this section, we are finalizing the interim final work RVUs. For CPT code 43263, we established an interim final work RVU based upon a crosswalk to CPT code 43262. As we detailed in the CY 2014 final rule with comment period, we valued CPT codes 43274, 43276, and 43278 using the same formula that the RUC used in determining its recommendations, but substituting our interim final work RVUs for codes used in the formula for the RUC-recommended values. CPT code 43277 was valued using the survey 25th percentile.

Comment: Commenters objected to our valuation of CPT 43263 based upon a crosswalk to CPT code 43262, saying that CPT 43263 is more intense and has greater risks than CPT code 43262. Commenters also indicated that we underestimated the intensity of CPT code 43276 indicating that CPT code 43276 typically involves replacing stents that are overgrown with cancerous tissues. They also said that we underestimated the intensity of CPT coded 43274 and 43277. Commenters further took issue with our valuing CPT code 43277 based upon the survey when most codes in this family were valued based upon the incremental formula. Commenters stated that CPT code 43278 is valued incorrectly because we did not correctly value CPT code 43229, which is used in the formula we used to value CPT code 43278.

Response: After consideration of the comments, we continue to believe that CPT code 43263 is the appropriate crosswalk for CPT code 43262 and we are finalizing a work RVU of 6.60 for that code. With regard to CPT code 43274, we continue to believe the formula described in the CY 2014 final

rule with comment period is the appropriate methodology. We are finalizing a work RVU of 8.58 for CPT code 43274 using the final values for the codes used in the formula and thus increasing the work RVU from the interim final value of 8.48. Similarly, we are finalizing a work RVU of 8.94 for CPT code 43276 based upon the formula described in the CY 2014 final rule with comment period adjusted for changes in the final work RVUs for values used in the formula. For CPT code 43277, we continue to believe the survey 25th percentile is appropriate. This valuation is supported by a drop in the intraservice time from the code it replaces. Thus, we are finalizing the interim final work RVU of 7.00. For CPT code 43278, we continue to believe use of the RUC formula for this code is most appropriate, and we are adjusting the work RVU to reflect final work RVUs for values used in the formula. The final work RVU for CPT code 43278 is 8.

(12) Spinal Injections (CPT Codes 62310, 62311, 62318 and 62319)

We proposed new work RVUs for these codes in the PFS proposed rule. (79 FR 40338–40339). See section II.B.3 for a discussion of the valuation of these codes, and a summary of public comments and our responses.

(13) Laminectomy (CPT Codes 63045, 63046, 63047 and 63048)

We established interim final work RVUs for CPT codes 63047 and 63048 for CY 2014. As we indicated in the CY 2014 final rule with comment period, we had identified CPT code 63047 as potentially misvalued through the high expenditure procedure code screen and the RUC included a recommendation for CPT code 63048. We noted that, to appropriately value these codes, we need to consider the other two codes in this family: CPT codes 63045 (Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; cervical) and 63046 (Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; thoracic). Although we did not receive recommendations for CPT codes 63045 and 63046, we established CY 2014 interim final work RVUs for CPT codes 63047 and 63048 of 15.37 and 3.47, respectively, based upon the RUC recommendations. We noted that we expected to review these values in concert with the RUC

recommendations for CPT codes 63045 and 63046 when we received them.

Comment: Commenters questioned our determination that CPT codes 63047, 63048, 63045 and 63046 constituted a family, noting that CPT codes 63045 and 63046 require different work. Commenters questioned the value of resurveying this set of codes as a family since CPT codes 63045 and 63046 constitute a small percentage of the total volume of these codes. The survey of CPT codes 63047 and 63048 did not reveal significant change in the values of the codes, and the work involved in resurveying would be burdensome for those involved. One commenter urged us to withdraw our request to survey these codes.

Response: We continue to believe that it is appropriate to value a family of codes together in order to maintain relativity. We also continue to believe that CPT codes 63045 and 63046 are indeed in the same family as CPT codes 63047 and 63048 due to similarity of service. We have received new RUC recommendations for CPT code 63045 and 63046, but did not receive them in time to include in this rule. As a result, we will finalize the interim work values for CPT codes 63047 and 63048 for CY 2015.

(14) Chemodenervation of Muscles (CPT Codes 64616, 64617, 64642, 64643, 64644, and 64645)

We assigned refined interim final work RVU values of 1.53 to CPT code 64616 and 1.90 to CPT code 64617. As detailed in the CY 2014 final rule with comment period, we refined the RUC-recommended work RVUs of 1.79 for CPT code 64616 and 2.06 for CPT code 64617 to reflect the deletion of an outpatient visit that was included in the predecessor code, CPT code 64613 (chemodenervation of muscle(s); neck muscle(s) (eg, for spasmodic torticollis, spasmodic dysphonia)). We also explained that since CPT code 64617, chemodenervation of the larynx, includes EMG guidance when furnished we determined the interim final work RVU by adding the work RVU for CPT code 95874 (Needle electromyography for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)) to the CY 2013 work RVU for CPT 64616.

For CY 2014, we assigned interim final work RVUs for CPT code 64643 and CPT code 64645 of 1.22 and 1.39, respectively. As we explained in the CY 2014 final rule with comment period, we refined the RUC-recommended work RVUs for these add-on codes by subtracting the RVUs to account for 19

minutes of pre-service time and the decrease in time for furnishing the add-on service. Additionally, we based the global period for these codes on the predecessor code, CPT code 64614 (chemodenervation of muscle(s); extremity and/or trunk muscle(s) (eg, for dystonia, cerebral palsy, multiple sclerosis)), which was deleted for CY 2014. Therefore, we assigned 10-day global periods to the services.

Comment: Most commenters disagreed with the CY 2014 interim final work RVU valuations for CPT codes 64616, 64643, and 64645. One commenter stated that the work RVU for the predecessor code, CPT code 64614, did not take into account the full level of intensity, time, and work that it takes to perform the service. This commenter also disagreed with the times for this service. Several commenters disagreed with the valuation of CPT code 64616 saying that we ignored the RUC recommendation which was based on survey data and RUC deliberations and asked that we value the code based upon the RUC recommendation. Several commenters disagreed with the valuations for CPT codes 64643 and 64645 saying that CMS did not explain our valuation, ignored the fact that the RUC discounted the add-on codes based on the pre- and post-service time and did not articulate any basis for our valuation decision. Several commenters requested refinement of the codes in the chemodenervation family.

Response: After consideration of the comments we are finalizing the interim final work RVUs and time for these codes. We continue to believe that our valuations for this family take into account the full level of intensity, time, and work that are required to furnish these services. Additionally, we disagree with commenters that we did not explain our valuation of CPT codes 64643 and 64645. In the CY 2014 final rule with comment period, we detail and thoroughly explain the methodology utilized to value CPT codes 64643 and 64645. Additionally, the request for refinement panel review was not granted as the criteria for refinement were not met.

(15) Impacted Cerumen (CPT Code 69210)

After it was identified as a potentially misvalued code pursuant to the CMS high expenditure screen, CPT code 69210, which describes removal of impacted cerumen, was revised from being applicable to “1 or both ears” to a unilateral code effective January 1, 2014. For Medicare purposes we limited the code to billing once whether it was furnished unilaterally or bilaterally

because we believed the procedure would typically be furnished in both ears as the physiologic processes that create cerumen impaction likely would affect both ears. Similarly, we continued the CY 2013 value as our interim final CY 2014 value since for Medicare purposes the service was unchanged.

Comment: Commenters requested that we allow CPT code 69210 to be billed twice when it is furnished bilaterally, consistent with code descriptor. Commenters stated that our assumption regarding the physiologic processes that create cerumen was flawed and requested we provide a clinical rationale and/or literature to support our claim. Lastly, the commenters requested guidance from the agency as to how best deal with this CPT code; specifically, if it should be sent to CPT for clarification or if not, that we provide further guidance as to how this procedure should be billed using the new code.

Response: We continue to believe that the procedure will be furnished in both ears as the physiologic processes that create cerumen impaction likely would affect both ears. As a result, we will continue to allow only one unit of CPT 69210 to be billed when furnished bilaterally and are finalizing our CY 2014 interim final work RVU for this service.

(16) Magnetic Resonance Imaging (MRI) Brain (CPT Codes 77001, 77002, and 77003)

As detailed in the CY 2014 final rule with comment period, we agreed with the RUC-recommended values for CPT codes 77001, 77002 and 77003 but were concerned that the recommended intraservice times for all three codes was generally higher than the procedure codes with which they were typically billed. We sought additional public comment and input from the RUC and other stakeholders regarding the appropriate relationship between the intraservice time associated with fluoroscopic guidance and the intraservice time of the procedure codes with which they are typically billed.

Comment: Some commenters disagreed with the concern expressed by CMS that the intraservice time for codes 77001, 77002 and 77003 is higher than the codes alongside which they are typically billed, as the commenters believed that the combinations being used to support this concern were not appropriate, and they requested additional examples to support its concern. The commenters believed that the concerns CMS expressed are unfounded and that we should assign work RVUs of 0.38, 0.54, and 0.60 for

CPT code 77001, 77002, and 77003, respectively.

Response: We continue to have concerns regarding the appropriate relationship between the intraservice time associated with fluoroscopic guidance and the intraservice time of the procedure codes with which they are typically billed and will continue to study this issue. We are finalizing the CY 2014 interim final values for CY 2015.

(17) Immunohistochemistry (CPT Codes 88342 and 88343 and HCPCS Codes G0461 and G0462)

These codes were revised for CY 2015. For discussion of valuation for CY 2015, see section II.G.3.b.

(18) Optical Endomicroscopy (Code 88375)

As detailed in the CY 2014 final rule with comment period, we believed that the typical optical endomicroscopy case would involve only the endoscopist, and CPT codes 43206 and 43253 were valued to reflect this. Accordingly, we believed a separate payment for CPT code 88375 would result in double payment for a portion of the overall optical endomicroscopy service. Therefore, we assigned a PFS procedure status of I (Not valid for Medicare purposes. Medicare uses another code for the reporting of and the payment for these services) to CPT code 88375.

Comment: Multiple commenters objected to CMS's decision to assign a PFS status indicator of "I" to code 88375, stating that the code already includes distinctions that would prevent a physician from billing the code when it would double count work. The commenters urge CMS to assign CPT code 88375 a Medicare status of A (Active Code), and to immediately publish RVUs associated with the service.

Response: In our re-review of this procedure and consideration of the information provided by commenters, we believe the coding is adequate to avoid double payment for a portion of the service. Accordingly, we assigned a Medicare status indicator of A (Active). To value this service, we based the RVUs on those assigned to CPT code 88329, adjusted for the difference in intraservice time between the two codes. We are assigning a final work RVU of 0.91 for CPT code 88375 for CY 2015.

(19) Speech Language (CPT Codes 92521, 92522, 92523 and 92524)

In CY 2014, we assigned CY 2014 interim final work RVUs of 1.75 and 1.50 for CPT codes 92521 and 92522,

respectively, as the HCPAC recommended. For CPT code 92523, we disagreed with the HCPAC-recommended work RVU of 3.36. We believed that the appropriate value for 60 minutes of work for the speech evaluation codes was reflected in CPT code 92522, for which the HCPAC recommended 1.50 RVUs. Because the intraservice time for CPT code 92523 was twice that for CPT code 92522, we assigned a work RVU of 3.0 to CPT code 92523. Similarly, since CPT codes 92524 and 92522 had identical intraservice time recommendations and similar descriptions of work we believed that the work RVU for CPT code 92524 should be the same as the work RVU for CPT code 95922. Therefore, we assigned a work RVU of 1.50 to CPT code 92524.

Comment: Commenters disagreed with the interim final work RVUs assigned to CPT codes 92523 and 92524, saying they based on inaccurate assumptions. Commenters stated that survey respondents appropriately took time and effort into account when valuing CPT code 92523 but had difficulty using a time-based reference code to value the RVU of an untimed code like CPT code 92523. Commenters noted that the HCPAC acknowledged that the work of the second hour involved in CPT code 92523 is indeed more intense than the first hour. Additionally, commenters stated that the work RVU reduction of CPT code 92524 was arbitrary because it was based solely on intraservice time and failed to recognize the more difficult aspects of performing the service compared to that of CPT code 92522. Commenters requested reconsideration of CPT codes 92523 and 92524 through refinement panel review.

Response: We believe that our interim final work RVU is most appropriate for these services. In the HCPAC recommendation for CPT code 92523 the affected specialty society stated that its survey results were faulty for this CPT code because those surveyed did not consider all the work necessary to perform the service. The commenters did not provide any information that demonstrates that our valuations fail to fully account for the intensity, work, and time required to perform these services. Therefore, we are finalizing our CY 2014 interim final values for CY 2015. We did not refer these codes to refinement because the request did not meet the criteria for refinement.

(20) Percutaneous Transcatheter Closure (CPT Code 93582)

As detailed in the CY 2014 final rule with comment period, we reviewed new

CPT code 93582. Although the RUC compared this code to CPT code 92941 (percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary), which has a work RVU of 12.56 and 70 minutes of intraservice time, it recommended a work RVU of 14.00, the survey's 25th percentile. We agreed with the RUC that CPT code 92941 is an appropriate comparison code and believed that due to the similarity in intensity and time that the codes should be valued with the same work RVU. Therefore, we assigned an interim final work RVU of 12.56 to CPT code 93582.

Comment: One commenter disagreed with the work RVU valuation of CPT code 93582 because they believed it did not accurately reflect the intensity of the procedure, particularly in treating infants. The commenter stated that the RUC concluded that a 55 percent work differential exists between performing this service on a child versus an adult—a fact that they stated supports the higher work RVU recommended by the RUC. As a result, the commenter suggests we assign the RUC-recommended work RVU to CPT code 93582. A commenter requested referral to the refinement panel.

Response: We continue to believe that CPT code 92941 is an appropriate comparison code to CPT code 93582 due to similarity in intensity and time and, as a result, the codes should be valued with the same work RVU. Therefore, we are finalizing our CY 2014 interim final work RVU of 12.56 to CPT code 93582 for CY 2015. We did not refer this code to refinement because the request did not meet the criteria for refinement.

(21) Duplex Scans (CPT Codes 93925, 93926, 93880 and 93882)

For CY 2014 we maintained the CY 2013 RVUs for CPT codes 93880 and 93882. We were concerned that the RUC-recommended values for CPT codes 93880 and 93882, as well as our final values for CPT codes 93925 (Duplex scan of lower extremity arteries or arterial bypass grafts; complete bilateral study) and 93926 (Duplex scan of lower extremity arteries or arterial bypass grafts; unilateral or limited study), did not maintain the appropriate relativity within the family and referred the entire family to the RUC to assess relativity among the codes and then recommend appropriate work RVUs. We also requested that the RUC consider CPT codes 93886 (Transcranial Doppler study of the intracranial arteries; complete study) and 93888 (Transcranial Doppler study of the

intracranial arteries; limited study) in conjunction with the duplex scan codes to assess the relativity between and among the codes.

Comment: One commenter questioned why we did not include all duplex scan codes we determined to be part of the family in our original request to the RUC. Another commenter opposed our valuation approach and stated that we should not redefine the codes in this family and that we should reject the RUC recommendations.

Response: The valuations for CPT codes 93880, 93882, 93925, 93926, 93886 and 93888 are included in this year's valuations in section II.G.3.b

(22) Interprofessional Telephone/Internet Consultative Services (CPT Codes 99446, 99447, 99448 and 99449)

In CY 2014 we assigned CPT codes 99446, 99447, 99448, and 99449 a PFS procedure status indicator of B (Bundled code. Payments for covered services are always bundled into payment for other services, which are not specified. If RVUs are shown, they are not used for Medicare payment). If these services are covered, payment for them is subsumed by the payment for the services to which they are bundled (for example, a telephone call from a hospital nurse regarding care of a patient) because Medicare pays for telephone consultations regarding beneficiary services as a part of other services furnished to the beneficiary.

Comment: A commenter expressed concern that the services covered by codes 99446–99449 were bundled together, and that no RVUs were published for these codes. The commenter observed that CMS compares the services to contact between nurses and patients in justifying its decision to bundle the services in with other work, and stated that this comparison is inappropriate to use regarding consultation between physicians. The commenter also stated that these services are vital in providing specific specialty expertise in areas where timely face-to-face service is not a viable option. The commenter urged that the status of these services be changed to “Active,” or at least “Non-covered,” and that the RUC-recommended values for these services be published.

Response: Medicare pays for telephone consultations regarding beneficiary services as part of other services furnished to a beneficiary. As a result, we continue to believe that CPT codes 99446–99449 are bundled; and we are finalizing the PFS procedure status indicator of B for these codes for CY 2015.

b. Finalizing CY 2014 Interim Direct PE Inputs

i. Background and Methodology

In this section, we address interim final direct PE inputs as presented in the CY 2014 PFS final rule with comment period and displayed in the final CY 2014 direct PE database available on the CMS Web site under the downloads at <http://www.cms.gov/PhysicianFeeSched/PFSFRN/list.asp#TopOfPage>.

On an annual basis, the RUC provides CMS with recommendations regarding PE inputs for new, revised, and potentially misvalued codes. We review the RUC-recommended direct PE inputs on a code-by-code basis. When we determine that the RUC recommendations appropriately estimate the direct PE inputs (clinical labor, disposable supplies, and medical equipment) required for the typical service and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the PE inputs to better reflect our estimate of the PE resources required for the service. We also confirm whether CPT codes should have facility and/or nonfacility direct PE inputs and refine the inputs accordingly.

In the CY 2014 PFS final rule with comment period (78 FR 74242), we addressed the general nature of some of our common refinements to the RUC-recommended direct PE inputs, as well as the reasons for refinements to particular inputs. In the following sections, we respond to the comments we received regarding common refinements we made based on established principles or policies. Following those discussions, we summarize and respond to comments received regarding other refinements to particular codes.

We note that the interim final direct PE inputs for CY 2014 that are being finalized for CY 2015 are displayed in the final CY 2015 direct PE input database, available on the CMS Web site under the downloads for the CY 2015 PFS final rule at www.cms.gov/PhysicianFeeSched/. The inputs displayed there have also been used in developing the CY 2015 PE RVUs as displayed in Addendum B of this final rule with comment period.

Comment: Commenters indicated that it would be helpful to have additional information about the specific rationale used in developing refinements, and specifically requested that CMS provide more information regarding how CMS makes the determination of whether an item is typical.

Response: We continually seek ways to increase opportunity for public comment. In response to comments received, we have provided more detailed explanations about refinements made for the CY 2015 interim final direct PE inputs. We recognize that we make assumptions about what is typical, and note that we welcome objective data that provides information about the typical case. We prefer that this information be submitted through the notice and comment rulemaking process. We also refer interested stakeholders to section II.F. of this final rule with comment period, in which we provide extensive discussion of the changes to the process that we are finalizing for valuing new, revised, and potentially misvalued codes.

ii. Common Refinements

(1) Equipment Time

Prior to CY 2010, the RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the RUC provide equipment times along with the other direct PE recommendations, and we provided the RUC with general guidelines regarding appropriate equipment time inputs. We continue to appreciate the RUC's willingness to provide us with these additional inputs as part of its PE recommendations.

In general, the equipment time inputs correspond to the service period portion of the clinical labor times. We have clarified this principle, indicating that we consider equipment time as the times within the intra-service period when a clinician is using the piece of equipment plus any additional time that the piece of equipment is not available for use for another patient due to its use during the designated procedure. For services in which we allocate cleaning time to portable equipment items, because the equipment does not need to be cleaned in the room that contains the remaining equipment items, we do not include that time for the remaining equipment items as they are available for use for other patients during that time. In addition, when a piece of equipment is typically used during any additional visits included in the global period for a service, the equipment time would also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the pre-service or post-service tasks performed by clinical labor staff on the day of the procedure

(the clinical labor service period) and are typically available for other patients even when one member of clinical staff may be occupied with a pre-service or post-service task related to the procedure.

Some commenters have repeatedly objected to our rationale for refinement of equipment minutes on this basis. We acknowledge the comments we received reiterating those objections to this rationale and refer readers to our extensive discussion in response to those objections in the CY 2012 PFS final rule with comment period (76 FR 73182). In the following paragraphs, we address new comments on this policy.

Comment: A commenter indicated that CMS removed minutes assigned to vascular ultrasound rooms for activities that CMS does not believe take place in the room, but CMS did not provide factual support for this assumption. The commenter further stated that CMS did not articulate the connection between the relevant data that the Administrative Procedures Act (APA) requires CMS to consider and the conclusion that CMS reached. The commenter indicated that they conducted a survey of a significant number of providers, in which most providers indicated that they performed these pre-service tasks in the room.

Response: We note that we would welcome comments that include vetted survey results, especially where the data are included. Statements regarding the existence of data to support commenters' assertions do not provide us with information to support conclusions based on the data. We acknowledge that we make assumptions about we believe to be typical. If there are data that support or refute these assumptions, we would be interested in reviewing that information. We would be most interested in reviewing survey data that address multiple points of our

assumptions regarding high-cost equipment, including how many procedures are furnished in a day, how often the equipment is being used, and other such information.

Comment: A commenter stated that CMS should publish, on a quarterly basis, refinements to the equipment times, rather than waiting until the final rule to publish these changes.

Response: We appreciate the commenter's concern about our making available timely information about refinements to practice expense inputs. We note that since we do not review and make refinements to practice expense inputs on a quarterly basis, we do not have information to publish on a quarterly basis. Rather, we have reviewed and refined practice expense recommendations from the RUC on an annual basis for the subset of codes for which recommendations have been provided to us. Because we have received many requests from stakeholders to publish our refinements as proposals in the proposed rule rather than in the final rule, we are finalizing a change in the process in which changes to RVUs and direct PE inputs will be included in the proposed rule rather than first appearing in the final rule with comment period. We refer readers to section II.F. of this final rule with comment period for further information about this change. We believe that this process will address commenters' concerns about having an opportunity to review these changes prior to the publishing of the final rule.

Comment: Several commenters asked that CMS identify what constitutes a highly technical piece of equipment.

Response: As we have previously indicated, during our review of all recommended direct PE inputs, we consider such items as the degree of specificity of a piece of equipment,

which may influence whether the equipment item is likely to be stored in the same room in which the clinical staff greets and gowns, obtains vitals, or provides education to a patient prior to the procedure itself. We would expect that items that are highly specific to particular procedures would be moved between rooms for those procedures. We also consider the level of portability (including the level of difficulty involved in cleaning the equipment item) to determine whether an item could be easily transferred between rooms before or after a given procedure. Items that are portable would also be expected to be moved between rooms. We also examine the prices for the particular equipment items to determine whether the equipment is likely to be located in the same room used for all the tasks undertaken by clinical staff prior to and following the procedure. We believe that highly expensive equipment would not be kept in a location that does not allow for its maximum utilization. For each service, on a case-by-case basis, we look at the description provided in the RUC recommendation and consider the overlap of the equipment item's level of specificity, portability, and cost; and, consistent with the review of other recommended direct PE inputs, we make the determination of whether the recommended equipment items are highly technical. We note that it is not practical to ensure that all of the existing equipment time in the database is allocated accordingly, but as we review any recommendations received from the RUC, we make this determination. To provide stakeholders with examples of the types of equipment items that are and are not considered highly technical, we have listed several items below and indicated whether they are highly technical.

TABLE 16—CLASSIFICATION OF HIGHLY TECHNICAL EQUIPMENT

Highly technical			Not highly technical		
Item	CMS code	Price	Item	CMS code	Price
room, CT	EL007	\$1,284,000.00	Light, exam	EQ168	\$1,630.12
accelerator, 6–18 MV	ER010	1,832,941.00	Table, exam	EF023	1,338.17
gamma camera system, single-dual head SPECT CT.	ER097	600,272.00	Chair, medical recliner	EF009	829.03

(2) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the pre-service, service period, and post-service clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks

described in the information that accompanies the recommended direct PE inputs, commonly called the “PE worksheets.” For most of these described tasks, there are a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures

with which it is typically reported. The RUC sometimes recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, CMS staff reviews the deviations from the standards to determine their appropriateness. When we do not accept

the RUC-recommended exceptions, we refine the interim final direct PE inputs to match the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M, we remove the pre-service clinical labor tasks to avoid duplicative inputs and to reflect the resource costs of furnishing the typical service.

In general, clinical labor tasks fall into one of the categories on the PE worksheets. In cases where tasks cannot be attributed to an existing category, the tasks are labeled “other clinical activity.” In these instances, CMS staff reviews these tasks to determine whether they are similar to tasks delineated for other services under the PFS. For those tasks that do not meet this criterion, we do not accept those clinical labor tasks as direct inputs.

(3) Equipment Minutes for Film Equipment Inputs

In section II.A. of this final rule with comment period, we finalize our proposal to accept the RUC recommendation to remove inputs associated with film technology that are associated with imaging services. We acknowledge comments received regarding the minutes allocated to equipment items associated with film technology; we will not address those comments below, because subsequent to the publication of the CY 2014 final rule with comment period, as discussed in section II.A. of this final rule with comment period, we finalized our proposal to remove these inputs from the Direct PE database, and thus the comments are no longer relevant.

(4) Standard Inputs for Moderate Sedation

In establishing interim final direct PE inputs for services that contain the standard moderate sedation input package, we refined the RUC’s recommendation by removing the stretcher (EF018) and adjusting the standard moderate sedation equipment inputs to conform to the standard moderate sedation equipment times. These procedures are listed in Table 17.

Comment: Commenters objected to our refinement of the standard moderate sedation equipment input times to conform to the moderate sedation equipment standard times, since it decreased the time allocated to these equipment items.

Response: We note that for moderate sedation procedures, the equipment time is tied to the RN time rather than to the entire service period. Specifically, this time includes 2 minutes for sedate/apply anesthesia, 100 percent of physician intraservice time, and 60 minutes of post-procedure time for every 15 minutes of RN monitoring time. The times included in Table 17 reflect this standard. We note that for all procedures in Table 17 the times allocated to the equipment items that were interim final for 2014 were already consistent with the moderate sedation standard equipment times, with the exception of CPT code 37238, which was mistakenly allocated 257 minutes, when the correct time is actually 242 minutes.

Comment: Commenters indicated that for office endoscopic procedures, the stretcher is typically used throughout the entire procedure, as well as during post-procedure monitoring. Other

commenters indicated that the stretcher is required during the moderate sedation recovery time. The commenters requested that we include the stretcher for those procedures, and that we reduce the increased time allocated to the power table.

Response: In section II.A. of this final rule with comment period, we finalized our proposal to modify the standard moderate sedation input package to include a stretcher for the same length of time as the other equipment items in the moderate sedation package. We indicated that the revised package would be applied to relevant codes as we review them through future notice and comment rulemaking. We have therefore refined those inputs to incorporate the stretcher for these codes listed in Table 17. Since we are incorporating the stretcher, we have removed the power table for procedures in which a power table was previously included. We will hold these procedures as interim final for CY 2015 due to the insertion of the stretcher and removal of the power table.

We are therefore finalizing the PE inputs for the procedures containing the standard moderate sedation inputs, with the additional refinements of including the stretcher for all of these procedures, removing the power table for the codes noted in Table 17 as containing a power table, and adjusting the equipment time for CPT code 37238. We note that these changes are displayed in the final CY 2015 direct PE input database, available on the CMS Web site under the downloads for the CY 2015 PFS final rule at www.cms.gov/PhysicianFeeSched/.

TABLE 17—CPT CODES WITH STRETCHER ADDED

CPT Code	Short descriptor	Moderate sedation	Contained power table?
10030	Guide cathet fluid drainage	152	
36245	Ins cath abd/l-ext art 1st	167	
37236	Open/perq place stent 1st	332	
37238	Open/perq place stent same	242	
37241	Vasc embolize/occlude venous	272	
37242	Vasc embolize/occlude artery	342	
37243	Vasc embolize/occlude organ	362	
37244	Vasc embolize/occlude bleed	332	
43200	Esophagoscopy flexible brush	77	Yes.
43201	Esoph scope w/submucous inj	80	Yes.
43202	Esophagoscopy flex biopsy	82	Yes.
43206	Esoph optical endomicroscopy	92	Yes.
43213	Esophagoscopy retro balloon	107	Yes.
43215	Esophagoscopy flex remove fb	82	Yes.
43216	Esophagoscopy lesion removal	84	Yes.
43217	Esophagoscopy snare les remv	92	Yes.
43220	Esophagoscopy balloon <30mm	82	Yes.
43226	Esoph endoscopy dilation	87	Yes.
43227	Esophagoscopy control bleed	92	Yes.
43229	Esophagoscopy lesion ablate	107	Yes.
43231	Esophagoscop ultrasound exam	107	Yes.

TABLE 17—CPT CODES WITH STRETCHER ADDED—Continued

CPT Code	Short descriptor	Moderate sedation	Contained power table?
43232	Esophagoscopy w/us needle bx	122	Yes.
43235	Egd diagnostic brush wash	77	Yes.
43236	Uppr gi scope w/submuc inj	82	Yes.
43239	Egd biopsy single/multiple	77	Yes.
43245	Egd dilate stricture	85	Yes.
43247	Egd remove foreign body	92	Yes.
43248	Egd guide wire insertion	82	Yes.
43249	Esoph egd dilation <30 mm	82	Yes.
43250	Egd cautery tumor polyp	82	Yes.
43251	Egd remove lesion snare	82	Yes.
43252	Egd optical endomicroscopy	92	Yes.
43255	Egd control bleeding any	92	Yes.
43270	Egd lesion ablation	107	Yes.
43450	Dilate esophagus 1/mult pass	77	Yes.
43453	Dilate esophagus	87	Yes.
49405	Image cath fluid colxn visc	162	
49406	Image cath fluid peri/retro	162	
49407	Image cath fluid trns/vgnl	167	

(5) Recommended PE Inputs Not Used in the Calculation of Practice Expense Relative Value Units

In preparing the Direct Practice Expense Input database for CY 2014, we noted that in some cases, there were recommended inputs in the database that were not used in the calculation of the PE RVUs. In cases where inputs are included for a particular service in a particular setting, but that service is not priced in that setting, the inputs are not used. In the documentation files for the CY 2014 final rule, we stated, “In previous years, we have displayed recommended inputs even when these inputs are not used in the calculation of the practice expense relative value units. We note that we are no longer displaying such inputs in these public use files since they are not used in the calculation of the practice expense relative value units that appear in the final rule.”

Comment: Some commenters objected to our removing practice expense inputs for services that were not reviewed for CY 2014.

Response: As indicated in the documentation files, the inputs removed were not used in the calculation of the PE RVUs. Therefore, their removal has no impact on the PE RVUs for these services or the payment for services. We remind readers that, from our perspective, the sole purpose of the Direct PE database is to establish PE RVUs. We believe it is more transparent for these inputs to not appear in the Direct Practice Expense Input database when they do not contribute to the PE RVU calculation for the relevant services.

iii. Code-Specific Direct PE Inputs

We note that we received many comments objecting to refinements made based on “CMS clinical review” (including our determination that certain recommended PE inputs were duplicative of others already included with the service), statutory requirements, or established principles and policies under the PFS. We note that for many of our refinements, the specialty societies that represent the practitioners who furnish the service objected to most of these refinements for the general reasons described above or for the reasons we respond to in the “background and methodology” portion of this section, or stated that they supported the RUC recommended PE inputs. Below, we respond to comments in which commenters address specific CPT/HCPCS codes and explain their objections to our refinements by providing us with new information supporting the inclusion of the items and/or times requested. When discussing these refinements, rather than listing all refinements made for each service, we discuss only the specific refinements for which commenters provided supporting information. We indicate the presence of other refinements by noting “among other refinements” after delineating the specific refinements for a particular service or group of services. For those comments that stated that an item was “necessary for the service” and provided no additional rationale or information, we conducted further review to determine whether the inputs as refined were appropriate and concluded that the inputs as refined were indeed appropriate. We also note that in many cases, commenters

objected to our indication that items were duplicative, stating that they did not know where the duplication existed. In future rulemaking, we do not intend to respond to comments where the commenters dispute the duplicative nature of inputs unless commenters specifically explain why the relevant items are not duplicative with the identical items included in a room, kit, pack, or tray. We expect that commenters will review the components of the room, kit, pack, or tray included for that procedure prior to commenting that the item is not duplicative. Finally, we note that in some cases we made proposals related to comments received in response to the CY 2014 final rule with comment period. In cases where we have addressed the concerns of commenters in the proposed rule, we do not respond to comments here as well.

(1) Cross-Family Comments

Comment: We received comments regarding refinements to equipment times for many procedures for which commenters indicated that the equipment time for the procedure should include the time that the equipment is unavailable for other patients, including while preparing equipment, positioning the patient, assisting the physician, and cleaning the room. Commenters also requested that we indicate which clinical labor tasks should be included in calculating the equipment time for highly technical equipment.

Response: As stated above, we agree with commenters that the equipment time should include the times within the intra-service period when a clinician is using the piece of equipment plus any

additional time the piece of equipment is not available for use for another patient due to its use during the designated procedure. We believe that some of these commenters are suggesting that we should allocate the full number of clinical labor minutes included in the service period to the equipment items. However, as we have explained, the clinical labor service period includes minutes based on some clinical labor tasks associated with pre- and post-service activities that we do not believe typically preclude equipment items from being used in furnishing services to other patients because these activities typically occur in other rooms. The equipment times allocated to the CPT codes in Table 18 already include the full intraservice time the equipment is typically used in furnishing the service, plus additional minutes to reflect time that the equipment is unavailable for use in furnishing services to other patients. In response to commenters request for clarification, Table 19 lists the standard clinical labor tasks to be included in the calculation of time allocated to highly technical equipment. We note that in some cases, some specialized intraservice clinical labor tasks are also

included in the equipment time calculations; we have not detailed every possible case in this table.

TABLE 18—EQUIPMENT INPUTS THAT INCLUDE APPROPRIATE CLINICAL LABOR TASKS ABOUT WHICH COMMENTS WERE RECEIVED

CPT Code	Equipment Items
70551	EL008
70552	EL008
70553	EL008
93880	EL016
93882	EL016

TABLE 19—CLINICAL LABOR TASKS INCLUDED IN CALCULATION OF EQUIPMENT TIME FOR HIGHLY TECHNICAL EQUIPMENT

Clinical Labor Task
Prepare room, equipment, supplies
Prepare and position patient
Assist physician in performing procedure and/or
Acquire images
Clean room/equipment by physician staff
Technologist QC's images in PACS, checking for all
images, reformats, and dose page

Comment: We received comments regarding refinements to clinical labor

times for several procedures, in which commenters indicated that CMS reduced the clinical labor minutes inappropriately for tasks related to film inputs, since the recommended minutes were based on the PEAC surveyed times. Tasks included “Process images, complete data sheet, present images and data to the interpreting physician” and “Retrieve prior appropriate imaging exams.”

Response: The surveyed times referenced by the commenters refer to the clinical labor tasks associated with film technology. In reviewing the times associated with these clinical labor tasks, we noted that it would be consistent with our policy finalized in this rule to adjust the times associated with clinical labor tasks for all interim final codes to be consistent with the RUC recommendations regarding clinical labor tasks for digital technology. We are making the associated changes and holding these direct PE inputs interim final for 2015. These clinical labor tasks associated with film and digital inputs are presented side-by-side, along with the range of typical times, in Table 20. The specific interim final codes and their time changes are listed in Table 21.

TABLE 20—CLINICAL LABOR TASKS ASSOCIATED WITH DIGITAL TECHNOLOGY

Service period	Clinical labor task: film inputs	Typical minutes	Clinical labor task: digital inputs	Typical minutes
Pre-Service	Retrieve prior appropriate imaging exams and hang for MD review, verify orders, review the chart to incorporate relevant clinical information and confirm contrast protocol with interpreting MD/Retrieve Prior Image for Comparison.	4 to 7	Availability of prior images confirmed Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocol by radiologist.	2 2
Service Period: Post-Service.	Process Images, complete data sheet, present images and data to the interpreting physician/Process films, hang films and review study with interpreting MD prior to patient discharge.	4 to 20 ...	Technologist QC's images in PACS, checking for all images, reformats, and dose page. Review examination with interpreting MD Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.	2 2 1

TABLE 21—INTERIM FINAL CODES WITH ADJUSTED CLINICAL LABOR TIMES DUE TO FILM-TO-DIGITAL MIGRATION

CPT code	CMS code	Total film task time (2014)	Total digital task time	Time change
19081	L043A	8	9	1
19082	L043A	5	5	0
19083	L051B	8	9	1
19084	L051B	5	*5	0
19085	L047A	8	9	1
19086	L047A	5	*5	0
19281	L043A	8	9	1
19282	L043A	5	*5	0
19283	L043A	8	9	1
19284	L043A	5	*5	0
19285	L051B	8	9	1
19286	L051B	5	*5	0
19287	L047A	8	9	1

TABLE 21—INTERIM FINAL CODES WITH ADJUSTED CLINICAL LABOR TIMES DUE TO FILM-TO-DIGITAL MIGRATION—Continued

CPT code	CMS code	Total film task time (2014)	Total digital task time	Time change
19288	L047A	5	*5	0
19281	L043A	5	5	0
19282	L043A	5	5	0
70450	L046A	10	9	-1
70460	L046A	11	9	-2
70470	L046A	13	9	-4
70551	L047A	6	9	2
70552	L047A	8	9	0
70553	L047A	8	9	0
72141	L047A	14	9	-5
72142	L047A	16	9	-7
72156	L047A	18	9	-9
72146	L047A	14	9	-5
72147	L047A	16	9	-7
72157	L047A	18	9	-9
72148	L047A	14	9	-5
72149	L047A	16	9	-7
72158	L047A	18	9	-9
74174	L046A	27	9	-22

* Add-on codes are allocated fewer minutes for these activities.

(2) Code-Specific Comments

(a) Destruction of Premalignant Lesions (CPT Codes 17000, 17003, 17004)

In establishing interim final direct PE inputs for CY 2014, CMS accepted the RUC's recommendations for supply item LMX 4% anesthetic cream (SH092).

Comment: Commenters indicated that the quantity of cream units in CPT code 17003 created a rank order anomaly with CPT codes 17000 and 17004, and that the inclusion of 3 grams was incorrect. Instead, 1 gram should have been included in CPT code 17003.

Response: We agree with the commenters that the quantity of SH092 in 17003 should be 1 gram. However, we also note that CPT code 17000 should also contain a quantity of 1 gram in order to avoid the rank order anomaly. After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT codes 17000, 17003, and 17004, with the additional refinement of changing the quantity of SH092 to 1 for CPT codes 17000 and 17003.

(b) Breast Biopsy (CPT Codes 19081, 19082, 19083, 19084, 19085, 19086, 19281, 19282, 19283, 19284, 19285, 19286, 19287, and 19288)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 19085, 19086, 19287, and 19288 by removing several new PE inputs, including items called "20MM handpiece—MR," "vacuum line assembly," "introducer localization set (trocar)," and "tissue filter," since we

concluded that these items served redundant clinical purposes with other biopsy supplies already included in the PE inputs for these codes. We also removed three new equipment items, described as "breast biopsy software," "breast biopsy device (coil)," and "lateral grid," because we determined that these items served clinical functions to items already included in the MR room.

Comment: Commenters indicated that the vacuum assisted breast biopsy requires an assisted biopsy needle system, and tubing must be run from the biopsy device to the biopsy control unit. Commenters also discussed supply items "introducer localization set (trocar)" and "tissue filter," stating that the trocar is used to target the biopsy on the correct lesion, and the tissue filter is necessary to remove the collected core samples from the collection chamber. Commenters described the importance of the "breast biopsy device (coil)," which is used to move one breast out of the way and the "breast biopsy software," which is required to make the necessary calculations to target and biopsy the lesions. Finally, commenters stated that the lateral grid is necessary to place the trocar correctly.

Response: The equipment item "breast biopsy device w-system (Mammotome)" (EQ074) is described as "an all-in-one platform designed for use under ultrasound, MRI, stereotactic and 3D image guidance" and is used with supply item "Mammotome probe" (SD094). Therefore, the supply items "20 MM handpiece," "vacuum line

assembly," "tissue filter," and "trocar," are duplicative of items already included in this procedure. We do note that we have used the invoice to create a price for equipment item "Breast biopsy device (coil)" (EQ371) at a price of \$12,238. After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT codes 19085, 19086, 19287, and 19288 as established with the additional refinement of incorporating the equipment item "Breast biopsy device (coil)" (EQ371).

Comment: A commenter noted that the new breast biopsy codes do not distinguish between the type of biopsy device used for the procedure, and that the cost of using the vacuum-assisted biopsy device (including a Mammotome probe, a Mammotome probe guide, and tubing and vacuum for the Mammotome device) is nearly eight times the cost of the equipment and supplies required to perform a standard (mechanical) core needle biopsy. The commenter noted that vacuum-assisted biopsy devices are predominantly used in stereotactic and MRI-guided breast biopsy procedures and 50 percent of the time in ultrasound-guided breast biopsy procedures.

Response: For a discussion about the change in coding, we refer readers to section II.F. of this final rule with comment period, where we finalize the work RVUs for interim final 2014 codes. With regard to the direct PE inputs for these services, we note that we include direct PE inputs based on the typical case, and since, as the commenter

points out, the vacuum-assisted biopsy devices are typically used, we include these items as direct PE inputs.

In reviewing the breast biopsy codes, we noted that we inadvertently included supply and equipment items related to breast biopsies in CPT codes 19283, 19284, 19285, 19286, 19087, and 19088, which are procedures that describe the placement of a localization device, not a biopsy. We will therefore remove the items listed in Table 22, which are currently included as direct PE inputs for these procedures. After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT codes 19081, 19082, 19083, 19084, 19085, 19086, 19281, 19282, 19283, 19284, 19285, 19286, 19287, and 19288 as established, with the additional refinements noted above.

TABLE 22—SUPPLY AND EQUIPMENT ITEMS INADVERTENTLY INCLUDED IN LOCALIZATION DEVICE PLACEMENT BREAST BIOPSY CODES

CPT	SD034	SC022	EQ074
19283	X	X
19284	X	X
19285	X
19286	X
19087	X	X	X
19088	X	X	X

(c) Nasal/Sinus Endoscopy (CPT Codes 31237, 31238)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 31237 and 31238 by refining the nurse blend (L037D) clinical labor time associated with task "Monitor pt. following service/check tubes, monitors, drains" from 15 minutes to 5 minutes.

Comment: Commenters stated that CMS should maintain consistency in the direct PE inputs across services by allocating the standard 15 minutes for every hour of post-procedure monitoring time. Commenters indicated that monitoring after these procedures is critical, since the risk of recurrent bleeding is high and patients may become lightheaded.

Response: There are two types of post-procedure monitoring time; a standard 15 minutes per hour of post-procedure monitoring time for moderate sedation, and a standard 15 minutes per hour of post-procedure monitoring time unrelated to moderate sedation. We understand the commenter's position to mean that there is 60 minutes of post-procedure monitoring required for these services (in accordance with the 15 minutes of RN time per 60 minutes of

monitoring). Because these procedures previously included 5 minutes of post-procedure monitoring time, we do not have a reason to believe that the monitoring time would have increased by 55 minutes. Should commenters believe this is the case, we invite commenters to provide information to justify this change. In cases where the specialty society is recommending post-procedure monitoring unrelated to moderate sedation, it is important that the recommendation clearly indicates the reason for the monitoring and the relationship between the clinical staff time and the monitoring time. After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT codes 31237 and 31238 as established.

(d) Implantation and Removal of Patient Activated Cardiac Event Recorder (CPT Codes 33282 and 33284)

In the CY 2013 final rule with comment period, in response to nomination of CPT codes 33282 and 33284 as potentially misvalued codes, we indicated that we did not consider the absence of pricing in a particular setting as an indicator of potentially misvalued codes. However, we requested that the RUC review these codes, including the work RVUs, for appropriate nonfacility and facility inputs.

Comment: A commenter expressed disappointment that CMS did not price these services in the nonfacility setting but did not provide further information about this decision.

Response: We received recommendations from the RUC for CPT codes 33282 and 33284 that did not include nonfacility inputs. Stakeholders who are interested in providing information about the direct PE inputs used in furnishing these services are welcome to submit this information to us; information about the level of information we seek is available to stakeholders in the sample PE worksheet available on the CMS Web site under downloads at <http://www.cms.gov/PhysicianFeeSched/PFSFRN/list.asp#TopOfPage>. We encourage commenters to submit the best data available on the appropriate inputs for these services.

(e) Transcatheter Placement of Intravascular Stent (CPT Codes 37236, 37237)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 37236 and 37237 by including supply item "catheter, balloon, PTA" (SD152) as a proxy for "balloon expandable"

because we believed that was an appropriate proxy. The invoices provided with the recommendation did not indicate the items on the PE worksheet with which they were associated.

Comment: The specialty society representing practitioners who furnish these services indicated that the item "balloon expandable" actually referred to a "balloon implantable stent," and that the invoices provided were associated with that item.

Response: We acknowledge the specialty society's clarification of the RUC recommendation. We will add item "balloon implantable stent" at a price of \$1,500, and remove the proxy item SD152. We note that when line items on the invoices provided are not clearly labeled, it is often difficult for us to determine how to relate the items on the PE spreadsheet with the items on the invoices. For specialty societies to ensure that the requested items are considered for inclusion in the relevant procedure codes, it is important that invoices accompany the RUC recommendations and the line items associated with items on the PE spreadsheet are clearly labeled.

After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT codes 37236 and 37237 as established with the additional refinement of including "balloon implantable stent" and removing "catheter, balloon, PTA" (SD152).

(f) Esophagoscopy (CPT Codes 43197 and 43198)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 43197 and 43198 to remove the Medical/Technical Assistant (L026A) time associated with clinical labor task "Clean Surgical Instrument Package," since no surgical instrument package is included in the service, and to remove the endoscopic biopsy forceps (SD066) from CPT code 43198, among other refinements.

Comment: Commenters acknowledged that the procedure did not contain a surgical instrument package, but stated that the time was still necessary for cleaning equipment, such as the nasal speculum, bayonette forceps, and biopsy forceps.

Response: In general, as a matter of relativity throughout the PFS, the time allocated for the standard clinical labor task "Clean room/equipment following procedure" encompasses time for cleaning all equipment items. The only exceptions to this rule are for equipment items that are tied to specific clinical

labor tasks, such as cleaning the surgical instrument pack or cleaning a scope. We do not believe it would serve relatively to separately break out time to clean various different types of equipment.

For the biopsy forceps, we indicated in the final rule with comment period that the information included with the RUC recommendation suggested that the biopsy forceps was reusable (as suggested by the cleaning time mentioned in this comment). As such, we have created a new equipment item based on the invoice provided with the recommendation and assigned 46 minutes to this equipment item. However, since we did not receive a paid invoice with this item, we will price it at \$0 until we receive a paid invoice.

After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT codes 43197 and 43198 as established, with the additional refinement of including 46 minutes for the reusable biopsy forceps.

(g) Esophagoscopy/Esophagoscopy Gastroscopy Duodenoscopy (EGD) (CPT Codes 43200, 43201, 43202, 43206, 43215, 43216, 43217, 43220, 43226, 43227, 43231, 43232, 43235, 43236, 43239, 43245, 43247, 43248, 43248, 43250, 43251, 43252, 43255, 43270)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 43200, 43201, 43202, 43206, 43215, 43216, 43217, 43220, 43226, 43227, 43231, 43232, 43235, 43236, 43239, 43245, 43247, 43248, 43248, 43250, 43251, 43252, 43255, and 43270 by refining the quantity of item "canister, suction" (SD009) from 2 to 1.

Comment: Commenters indicated that, for patient safety reasons, one suction canister is needed for the mouth, and another for the scope for patient safety reasons. Other stakeholders, specifically, several specialty societies with whom we met during the comment period, informed us that one suction canister is sufficient and typical for these services.

Response: We are persuaded by the information provided by the medical specialty societies during the comment period who indicated that one suction canister is typical.

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 43201 by removing needle, micropigmentation (tattoo) (SC079), as the needle required for this procedure needs to go through an endoscope, and no invoice was provided for this item.

Comment: Commenters indicated that the tattoo needle was required to mark the site for injection.

Response: We did not receive an invoice for the tattoo needle and have no information about this item. We are also unable to include this item in the PE calculations without a method to price it. We do not believe that we have a reasonable proxy at this time. If we receive invoices for this item, we will be able to include it in the direct PE input database.

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 43201, 43220, 43226, and 43231 by removing supply item "cup, biopsy-specimen non-sterile 4oz" (SL035).

Comment: Commenters indicated that the endoscopy base code, 43200, is included in all of these procedures. Since the biopsy cup is included in the endoscopy base code, it should be included for these codes as well.

Response: We agree with commenters that it is appropriate to include this supply item for these procedures. We will include the supply item "cup, biopsy-specimen non-sterile 4oz" in the direct PE inputs for these procedures.

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT code 43220 by substituting supply item "SD019" as a proxy for "SD025."

Comment: Commenters requested that we include "endoscopic balloon, dilation" (SD287) rather than a proxy, as this supply item is now included in the database.

Response: After receiving clarification regarding this request, we agree with commenters that SD287 is an appropriate supply input for this procedure. Therefore, we will include SD287 for CPT code 43220.

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 43220, 43249, and 43270 by removing supply item "guidewire, STIFF" (SD090), among other refinements.

Comment: Commenters indicated that the guidewire is required to safely straddle tumors for which there is impaired visibility and an inability to pass the scope through.

Response: We agree with commenters that it would be appropriate to include supply item "guidewire—STIFF" in these procedures. We will include the supply item "guidewire—STIFF" in the direct PE inputs for these procedures.

After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for codes 43200, 43201, 43202, 43206, 43215, 43216, 43217, 43220, 43226, 43227,

43231, 43232, 43235, 43236, 43239, 43245, 43247, 43248, 43248, 43250, 43251, 43252, 43255, and 43270 as established, with the additional refinements of including the supply items noted above.

(h) Dilation of Esophagus (CPT Codes 43450, 43453)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 43450 and 43453 by removing equipment item "endoscope disinfectant, rigid or fiberoptic, w-cart" (ES005), and not creating a new item "mobile stand, vital signs monitor," and other refinements.

Comment: Commenters stated that the endoscope disinfectant is a necessary part of all endoscopic procedures for sanitary and safety reasons, and that it should be restored for all gastrointestinal endoscopy codes. Commenters also noted that the mobile stand is the standard method of monitoring that must be moved along with the patient.

Response: Since these are non-endoscopic dilation codes, there is no scope to clean, and thus the endoscope disinfectant is unnecessary. The standard inputs for moderate sedation as recommended by the RUC were included in this procedure; the mobile stand overlaps with the standard moderate sedation input items. After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for codes CPT codes 43450 and 43453 as established.

(i) Spinal Injections (CPT Codes 62310, 62311, 62318, 62319)

In establishing interim final direct PE inputs for CY 2014, CMS accepted the RUC recommendations for CPT codes 62310, 62311, 62318, and 62319. Based on comments received, we made a proposal to maintain the CY 2014 direct PE inputs for CY 2015 while the codes are reexamined for bundling. We are finalizing this proposal, so while we acknowledge comments received on these codes, we will not respond to these comments as the interim final inputs to which the comments relate will not be used for 2015.

(j) Percutaneous Implantation of Neurostimulator (CPT Code 63650)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT code time by removing the time associated with clinical labor task "Clean Surgical Instrument Package" and removing supply item "pack, cleaning, surgical instruments" (SA043) since no surgical

instrument package is included in the service.

Comment: Commenters indicated that clinical staff time is critical for the safety and efficiency of the procedure, and that the surgical instrument cleaning package is necessary to ensure proper adherence of the electrodes.

Response: In general, as a matter of relativity throughout the PFS, the time allocated for the standard clinical labor task “Clean room/equipment following procedure” encompasses time for cleaning all equipment items. The only exceptions to this rule are for equipment items which are tied to specific clinical labor tasks, such as cleaning the surgical instrument pack or cleaning a scope. We do not believe it would serve relativity to separately break out time to clean various different types of equipment. After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT code 63650 as established.

(k) Chemodenervation (CPT Codes 64616, 64642, 64644, 64646, 64647)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC’s recommendations for CPT codes 64616, 64642, 64644, 64646, and 64647 by reducing the minutes allocated to “table, exam” (EF023) and removing the time associated with clinical labor task “Complete botox log,” as well as reducing the L037D time for clinical labor “assist physician performing procedure” for CPT code 64616, among other refinements.

Comment: One commenter opposed our adjusting the minutes allocated to the exam table. Commenters stated that the reference code, 64615, included three minutes of clinical labor time for “complete botox log,” and requested that they be included since they are in the reference code. One commenter asked whether CMS planned to remove the minutes from the reference code as well. Other commenters indicated that as with most injections, it is necessary to document various elements of information for safety purposes.

Response: Upon reviewing the time allocated to the exam table, we noted that our standard equipment policy is to allocate the entire service period for equipment that is not highly technical. Therefore, we will allocate minutes for

the entire service period for the exam table, as follows: 28 minutes for 64616, 44 minutes for 64642, 49 minutes for 64644, 44 minutes for 64646, and 49 minutes for 64647. We appreciate commenters pointing out the three minutes of time inadvertently allocated for “complete botox log” in the reference code, 64615, and will consider this issue in future rulemaking. We note that one of the benefits of having information stored in the direct PE database at the clinical labor task level is that it allows us to make comparisons of codes under review to existing codes in the PE database. This will help us ensure greater consistency in our refinements. As commenters point out, various injections are documented in logs, rather than medical records. The use of a different location for documentation is not a reason to allocate additional clinical labor time for a particular service.

Comment: One commenter supported our adjustment of “assist physician” time from 7 minutes to 5 minutes. Another commenter disagreed with the refinement and requested that CMS explain how physician time was calculated, while a different commenter stated that the “assist physician” time should be 28 minutes.

Response: Upon reviewing the work time and the time allocated for assist physician, we determined that 7 minutes is actually appropriate for the assist physician task.

After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT codes 64616, 64642, 64644, 64646, and 64647 as established, with the additional refinement of adjusting the minutes for the exam table as indicated above and adding 2 minutes of clinical labor for the “assist physician” task for 64616.

(l) MRI Brain (CPT Codes 70551, 70552, 70553)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC’s recommendations for CPT codes 70551, 70552, and 70553 by adjusting the time for clinical labor task “assist physician in performing procedure/acquire images,” removing 2 minutes of clinical labor time for clinical labor task “escort patient from exam room due to

magnetic sensitivity,” removing supply items “gauze,sterile 2in x 2in” (SG053), “tape, phix strips (for nasal catheter)” (SG089), “povidone swabsticks (3 pack uou)” (SJ043), and “swab-pad, alcohol” (SJ 053) from CPT codes 70552 and 70553, among other refinements.

Comment: Commenters indicated that the times associated with clinical labor task “assist physician in performing procedure/acquire images” reflected the PEAC surveyed times, and they had no reason to believe that the time had decreased since the PEAC review.

Response: As indicated in the PFS CY 2014 final rule with comment period (78 FR 74345), the procedure time for these services was last reviewed in 2002. We noted that we believe there should be no significant difference between the time to acquire images for an MRI of the brain and an MRI of the spine, and that, rather than rely on very old survey data, it would be appropriate to crosswalk the time associated with the MRI of the spine to the MRI of the brain. We continue to believe that this time is more accurate than that of the survey data.

Comment: Commenters noted that the clinical labor task “escort patient from exam room due to magnetic sensitivity” is a necessary activity for patient safety.

Response: Upon review of this clinical labor task, we noted that this task was included in the PE worksheets from when these codes were previously reviewed in 2002. Therefore, since this activity does not reflect a newly added clinical labor task, we agree with commenters that it would be appropriate to include 2 minutes for this clinical labor task.

Comment: Commenters stated that the supplies removed from CPT codes 70552 and 70553 were necessary supplies for the service, and that the specialty society incorrectly included supply item “tape, phix strips (for nasal catheter)” (SG089), when the correct supply item was “tape, surgical paper 1in (Micropore)” (SG079).

Response: We note that these supplies were removed because they were already contained in the supply item “kit, IV starter” (SA019). Table 23 shows the items contained in the IV starter kit and the corresponding supply items removed due to redundancy.

TABLE 23—ITEMS REMOVED FOR REDUNDANCY AND PARALLEL ITEMS INCLUDED IN IV STARTER KIT

Items in IV starter kit	Corresponding items removed for redundancy
1 tourniquet	
1 PVP ointment	povidone swabsticks (3 pack uou)
1 PVP prep pad	swab-pad, alcohol

TABLE 23—ITEMS REMOVED FOR REDUNDANCY AND PARALLEL ITEMS INCLUDED IN IV STARTER KIT—Continued

Items in IV starter kit	Corresponding items removed for redundancy
2 gauze sponges	gauze, sterile 2in x 2in
1 bandage (1"x3")	
1 sm roll surgical tape	tape, surgical paper 1in
1 pr gloves	
1 underpad 2ft x 3ft (Chux)	

After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT codes 70551, 70552, and 70553, with the additional refinement of including 2 minutes of clinical labor time as noted above.

(m) MRI Spine (CPT Codes 72141, 72142, 72146, 72147, 72149, 72156, 72157, 72158)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 72141, 72142, 72146, 72147, 72149, 72156, 72157, and 72158 by removing 2 minutes of clinical labor time for clinical labor task "escort patient from exam room due to magnetic sensitivity," and other refinements.

Comment: Commenters noted that the clinical labor task "escort patient from exam room due to magnetic sensitivity" is a necessary activity for patient safety.

Response: Upon review of this clinical labor task, we noted that this task was included in the PE worksheets from when these codes were previously reviewed in 2002. Therefore, since this activity does not reflect a newly added clinical labor task, we agree with commenters that it would be appropriate to include 2 minutes for this clinical labor task.

Comment: A commenter noted that CMS did not include a contrast imaging pack, which includes supplies necessary for contrast enhanced studies.

Response: In section II.B. of this final rule with comment period, we finalized our policy to add a contrast imaging pack to be used for imaging services with contrast. Therefore, we will include the contrast supply pack (CMS code SA114) for CPT codes 72142, 72147, 72149, 72156, 72157, and 72158.

After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT codes 72141, 72142, 72146, 72147, 72149, 72156, 72157, and 72158, with the additional refinement of including 2 minutes of clinical labor time and including the supply pack for the services noted above.

(n) Selective Catheter Placement (CPT Code 75726)

In establishing interim final direct PE inputs for CY 2014, when reviewing CPT code 36245, which was identified through a misvalued code screen of codes reported together more than 75 percent of the time, we noted that it was frequently billed with 75726. We then noted that these two services had identical time for "assist physician in performing procedure," and since the time for 36245 was reduced from 73 to 45 minutes, refined the clinical labor time for 75726 to correspond to this change.

Comment: Commenters indicated that the 73 minutes reflected the PEAC surveyed times, and that these activities are imaging-related, and in addition to the time and activities inherent in the accompanying surgical base code.

Response: As indicated elsewhere in this section, we note that the PEAC survey data are very old, and that refinements based on more updated information are appropriate. We continue to believe that it is appropriate for the intraservice times for 36245 and 75726 to continue to correspond to one another, as they are frequently furnished together. After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT code 75726 as established.

(o) Radiation Treatment Delivery (CPT Codes 77373, 77422, 77423)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT code 77373 by refining the equipment time for "pulse oximeter w-printer" (EQ211) and "SRS system, SBRT, six systems, average" (ER083) to conform to established equipment policies.

Comment: Commenters stated that the times should be maintained at 104 minutes, rather than being reduced to 86 minutes, and indicated the clinical labor task lines that should be included in the calculations.

Response: Upon reviewing the equipment times associated with this procedure, we agree with commenters that the time allocated for the

equipment should include the time associated with the indicated clinical labor tasks for these equipment items. After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT code 77373 as established, with the additional refinement of adjusting the equipment times to 104 minutes as noted above.

For CY 2014, we also eliminated several anomalous supply inputs included in the direct PE database, which affected 77422 and 77423, among other services.

Comment: Commenters indicated that upon reviewing the inputs for these services, they noted that the Record and Verify System and the laser targeting system were missing in both of these services, despite being in the original 2005 recommendation.

Response: We appreciate the commenters' attention to detail. However, as indicated elsewhere, we do not believe that the record and verify system is medical equipment used in furnishing the technical component of the service. We refer readers to our discussion of this issue in the PFS 2014 Final rule with Comment period (78 FR 74317). Further, since these codes have not been reviewed in many years, we do not know if the laser targeting system continues to be an appropriate input for these services. Therefore, we request that the RUC examine the inputs for these services to ensure their accuracy.

(p) Hyperthermia (CPT Code 77600)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT code 77600 by refining the time allocated to equipment item "hyperthermia system, ultrasound, external" (ER035) and removing the time associated with clinical labor task "clean scope," among other refinements.

Comment: Commenters indicated that the appropriate lines were not used to calculate the recommended equipment times, including cleaning the scope and check dressing.

Response: Upon reviewing the comments, we re-examined the equipment time calculation and

continue to believe that the time allocated to this equipment item is appropriate. We note that there is no scope used in this procedure, so time to clean the scope is unnecessary. After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT code 77600 as established.

(q) High Dose Rate Brachytherapy (CPT Codes 77785, 77586, 77787)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 77785, 77786, and 77787 to remove "Emergency service container—safety kit," as we consider it an indirect PE.

Comment: Commenters noted that the emergency container is a safety device used when a source must be retrieved manually. Commenters indicated that it is a mobile item and that the service cannot be provided unless it is in the room, and thus it is a direct PE, since it is directly assumed by a physician in the course of providing the service. Commenters asked that we reclassify this item as a direct input.

Response: In our clinical review, we reviewed the work vignettes for these procedures, which did not include the use of the "emergency service container—safety kit" as a part of the procedure. Although we acknowledge that the emergency service container safety kit needs to be readily available during the procedure, we note that "standby" equipment, or items that are not used in the typical case, are considered indirect costs. For further discussion of this issue, we refer readers to our discussion of "standby" equipment in the CY 2001 PFS proposed rule (65 FR 44187).

When reviewing the interim final direct PE inputs for these services, we noted that the specialty societies conducted a survey of the technicians, which revealed higher procedure times than the current procedure times. However, since the RUC indicated that they did not have "compelling evidence," the specialty society did not request the higher procedure times. We believe that if the specialty society believes that the code is undervalued relative to the expert panel value, and there is no indication that the survey was flawed, the specialty society should recommend the use of the surveyed procedure times. In doing so, the specialty society would give CMS the opportunity to consider the information provided alongside the RUC recommended times. We believe that surveys of technicians have the potential to be more accurate, rather than less accurate, than those of

physicians, as the technicians do not have incentives to increase the surveyed time. We suggest that rather than attempting to insert items that are not standard in the PE methodology, that specialty societies make a strong, data-driven case, for why the survey times are correct.

Comment: A commenter noted that there have been significant reductions to these CPT codes over the last several years, and urged CMS to phase in the reductions over time should the reductions be deemed appropriate after review of the methodology and data.

Response: We note that reductions to CPT codes are made on the basis that they are potentially misvalued. We do not typically transition such reductions. However, the Protecting Access to Medicare Act (PAMA) requires that beginning in 2017, CMS transition code-level reductions of greater than or equal to 20 percent in a given year; therefore, beginning in 2017, such reductions will be transitioned.

After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT codes 77785, 77786, and 77787 as established.

(r) Cytopathology (CPT Code 88112)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT code 88112 by removing the clinical labor time associated with several clinical labor tasks, including "Order, restock, and distribute specimen containers with requisition forms," "Perform screening function (where applicable)," "Confirm patient ID, organize work, verify and review history," and "Enter screening diagnosis in laboratory information system, complete workload recording logs, manage any relevant utilization review/quality assurance activities and regulatory compliance documentation and assemble and deliver slides with paperwork to pathologist."

Comment: Commenters pointed out that CPT code 88112 was inadvertently listed in Table 28 in the CY 2014 final rule with comment period as being unrefined by CMS. Commenters also opposed the reductions in clinical labor time, and noted that the PE subcommittee thoroughly reviewed these inputs.

Response: We apologize for the inadvertent inclusion of CPT code 88112 in Table 28 of the CY 2014 final rule with comment period. We re-examined the clinical labor tasks in light of the comments received and noted that the clinical labor task "Order, restock, and distribute specimen containers with requisition forms" is

not a clinical labor task associated with furnishing a service to a particular patient, and is therefore allocated in the indirect practice expense. Clinical labor task "Perform screening function (where applicable)" is not a task completed in the typical service, and is therefore not included. Further, clinical labor task "Confirm patient ID, organize work, verify and review history" is subsumed within clinical labor task "Remove slide from coverslipper; confirm patient ID, organize work, send slides to cytotech for screening"; including both would therefore be duplicative. Clinical labor task "Enter screening diagnosis in laboratory information system, complete workload recording logs, manage any relevant utilization review/quality assurance activities and regulatory compliance documentation and assemble and deliver slides with paperwork to pathologist" involves quality assurance activities. We refer readers to the CY 2014 PFS final rule with comment period (78 FR 74308) for a discussion regarding quality assurance activities. After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT code 88112.

Comment: One commenter noted that the refinements to the PE inputs for CPT code 88112 resulted in a rank-order anomaly, as CPT code 88108 has higher PE RVUs than CPT code 88112, while CPT code 88108 is a less complex service than CPT code 88112. Specifically, commenters stated that it is illogical for a cytology specimen processing technique that involves an additional step that requires materially more resources to have an RVU that is less than an associated technique that requires fewer resources, and expressed concerns about the potential for misreporting.

Response: We appreciate this commenter bringing this rank order anomaly to our attention. As indicated in section II.B. of this final rule with comment period, we are referring this code to the RUC as potentially misvalued based on the information received from the commenter.

(s) Duplex Scans (CPT Codes 93880 and 93882)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 93880 and 93882 by removing the equipment time allocated for equipment items "video SVHS VCR (medical grade)" (ED034) and "video printer, color (Sony medical grade)" (ED036), and refining the equipment time for "computer desktop, w-monitor"

(ED021) from 68 to 51 minutes, among other refinements.

Comment: Commenters indicated that these items are not redundant and asked that CMS explain which items encompass ED034 and ED036. Commenters also stated that the desktop computer is used for the entire intraservice period. Commenters also stated that the refinements were expressed as a final decision effective January 1, 2014.

Response: The equipment item “room, vascular ultrasound” (EL016) contains “room, ultrasound general” (EL015), which contains both “video SVHS VCR (medical grade)” and “digital printer (Sony UPD21).” We also note that the RUC has reviewed these codes again for 2015; we refer readers to section II.F. of this rule for further discussion, including the new interim final inputs established for 2015. We further note that contrary to the commenters’ assertion, the refinements made were indeed effective January 1, 2014, but were not final decisions; rather, they were interim final for 2014 and subject to public comment.

(t) Electroencephalogram (CPT Codes 95816, 95819, 95822)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC’s recommendations for CPT codes 95816, 95819, and 95822 by refining the equipment time allocated to equipment item “EEG, digital, testing system (computer hardware, software & camera)” (EQ330), among other refinements.

Comment: Commenters indicated that various staff activities are performed on the computer and requested that we restore the time previously removed.

Response: Upon reviewing comments regarding the equipment time, we agree with commenters that we should allocate the entire service period for EQ330, since it is not highly technical equipment. After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT codes 95816, 95819, and 95822 as established, with the additional refinement of assigning the intraservice time to EQ330.

(u) Anogenital Examination With Colposcopic Magnification in Childhood for Suspected Trauma (CPT Code 99170)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC’s recommendations for CPT codes, we accepted the RUC’s recommendation to include a new clinical labor type called “child life specialist.”

Comment: One commenter supported the inclusion of clinical labor staff time for the child life specialist.

Response: We appreciate the commenter’s support for this decision. After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT code 99170 as established.

(v) Immunohistochemistry (HCPCS Codes G0461 and G0462)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC’s recommendations for CPT codes 88342 and 88343 by creating G-codes G0461 and G0462 and refining the inputs for these services. We acknowledge comments regarding the refinements CMS made to these inputs, as well as comments indicating that the direct practice expense inputs for these procedures implied that the reporting would be different than the reporting implied by the code descriptors. We note that the RUC has subsequently reviewed CPT codes 88342 and 88343 again and we present the interim final values for 2015 in this final rule with comment period. Therefore, we will not address specific comments regarding G0461 and G0462 except, as discussed below, as they pertain to errors identified with regard to the pricing of supplies.

Comment: Commenters alerted us to an error in the calculation of the supply price for SL483 and SL486. Commenters pointed out that the price for SL483 is \$22.56/ml, rather than the .00256/ml that was listed in the database, and based on the unit of measure established in the direct PE inputs database for SL486, which costs \$65.63 for 250 tests, the per test quantity should be 1, rather than 0.004.

Response: We agree with commenters that these prices were calculated incorrectly and have made the adjustments to the direct PE database.

c. Finalizing CY 2014 Interim Malpractice Crosswalks for CY 2015

In accordance with our malpractice methodology, we adjusted the malpractice RVUs for the CY 2014 new/revised/potentially misvalued codes for the difference in work RVUs (or, if greater, the clinical labor portion of the PE RVUs) between the source codes and the new/revised codes to reflect the specific risk-of-service for the new/revised codes. The interim final malpractice crosswalks were listed in Table 30 of the CY 2014 PFS final rule with comment period.

We received only one comment on our CY 2014 interim final cross walks. As detailed in the CY 2014 final rule

with comment period, we assigned malpractice crosswalk of CPT code 31575 (Laryngoscopy, flexible fiberoptic; diagnostic) to CPT codes 43191–43195 and CPT code 31638 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with revision of tracheal or bronchial stent inserted at previous session (includes tracheal/bronchial dilation as required)) to CPT code 43196.

Comment: A commenter said that the established PLI crosswalk, CPT code 31575, for CPT code 43191–43196 is not appropriate because the latter services have a life-threatening risk to patients and the same is not true for CPT code 31575. The commenter recommends instead that we utilize the RUC recommended crosswalk of bronchoscopy, rigid or flexible codes (CPT codes 31622 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing, when performed (separate procedure)) for CPT code 43191, 31625 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial or endobronchial biopsy(s), single or multiple sites) for CPT code 43192, 43193, and 43195, and 31638 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with revision of tracheal or bronchial stent inserted at previous session (includes tracheal/bronchial dilation as required)) for CPT codes 43194 and 43196.

Response: We continue to believe that our assigned CY 2014 malpractice crosswalks best define the malpractice risk associated with CPT codes 43191–43196. Therefore, we are finalizing our CY 2014 interim final crosswalks.

We received no comments on the CY 2014 interim final malpractice crosswalks and are finalizing them without modification for CY 2015.

The malpractice RVUs for these services are reflected in Addendum B of this CY 2014 PFS final rule with comment period. Since we are finalizing a five-year review of MP RVUs in this final rule with comment period, the MP RVUs assigned to this codes will also be affected by the updates due to this review. For details on the review, see section II.C.

d. Other New, Revised or Potentially Misvalued Codes with CY 2014 Interim Final RVUs Not Specifically Discussed in the CY 2015 Final Rule With Comment Period

For all other new, revised, or potentially misvalued codes with CY 2014 interim final RVUs that are not

specifically discussed in this CY 2015 PFS final rule with comment period, we are finalizing for CY 2015, without modification, the CY 2014 interim final or CY 2014 proposed work RVUs, malpractice crosswalks, and direct PE inputs. Unless otherwise indicated, we agreed with the time values recommended by the RUC or HCPAC for all codes addressed in this section. The

time values for all codes are listed in a file called “CY 2014 PFS Work Time,” available on the CMS Web site under downloads for the CY 2015 PFS final rule with comment period at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>.

3. Establishing CY 2015 RVUs

a. Finalizing CY 2015 Proposed RVUs

In the CY 2015 proposed rule, we proposed CY 2015 work values for several codes. Table 24 contains a list of these codes and the final CY 2015 work RVUs. For more information on these codes and the establishment of the values, see section II.B of this final rule with comment period.

TABLE 24—CY 2015 FINAL WORK RVUS FOR CODES WITH PROPOSED WORK RVUS

HCPSC code	Long descriptor	CY 2014 WRVU	Proposed CY 2015 work RVU	CY 2015 work RVU
G0389 ..	Ultrasound, B-scan and/or real time with image documentation; for abdominal aortic aneurysm (AAA) screening.	0.58	0.58	0.58
G0416 ..	Surgical pathology, gross and microscopic examination for prostate needle biopsies, any method;	3.09	3.09	3.09
G0473 ..	Face-to-face behavioral counseling for obesity, group (2–10), 30 minutes	(1)	N/A	0.25
62310 ...	Injection(s), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; cervical or thoracic.	1.18	1.91	1.91
62311 ...	Injection(s), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; lumbar or sacral (caudal).	1.17	1.54	1.54
62318 ...	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, includes contrast for localization when performed, epidural or subarachnoid; cervical or thoracic).	1.54	2.04	2.04
62319 ...	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, includes contrast for localization when performed, epidural or subarachnoid; lumbar or sacral (caudal).	1.50	1.87	1.87
77055 ...	mammography; unilateral,70	.70	.70
77056 ...	mammography; bilateral87	.87	.87
77057 ...	screening mammography, bilateral (2-view film study of each breast)70	.70	.70
99490 ...	Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored.	New	.61	.61

¹ New.

b. Establishing CY 2015 Interim Final Work RVUs

Table 25 contains the CY 2015 interim final work RVUs for all codes for which we received RUC recommendations for CY 2015 and G-codes with interim final

values for CY 2015. These values are subject to public comment. The column labeled “CMS Time Refinement” indicates whether CMS refined the time values recommended by the RUC or HCPAC.

This section discusses codes for which the interim final work RVU or time values assigned for CY 2015 vary from those recommended by the RUC or for which we do not have RUC recommendations.

TABLE 25—CY 2015 INTERIM FINAL WORK RVUS FOR NEW/REVISED OR POTENTIALLY MISVALUED CODES

HCPSC Code	Long descriptor	CY 2014 WRVU	RUC/HCPAC recommended work RVU	CY 2015 work RVU	CMS time refinement
11980	Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin).	1.48	1.10	1.10	No
20604	Arthrocentesis, aspiration and/or injection, small joint or bursa (eg, fingers, toes); with ultrasound guidance, with permanent recording and reporting.	(1)	0.89	0.89	No

TABLE 25—CY 2015 INTERIM FINAL WORK RVUS FOR NEW/REVISED OR POTENTIALLY MISVALUED CODES—Continued

HCPSC Code	Long descriptor	CY 2014 WRVU	RUC/ HCPAC recommended work RVU	CY 2015 work RVU	CMS time refinement
20606	Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (eg, temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); with ultrasound guidance, with permanent recording and reporting.	(1)	1.00	1.00	No
20611	Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); with ultrasound guidance, with permanent recording and reporting.	(1)	1.10	1.10	No
20983	Ablation therapy for reduction or eradication of 1 or more bone tumors (eg, metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; cryoablation.	(1)	7.13	7.13	No
21811	Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 1–3 ribs.	(1)	19.55	10.79	Yes
21812	Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 4–6 ribs.	(1)	25.00	13.00	Yes
21813	Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 7 or more ribs.	(1)	35.00	17.61	Yes
22510	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic.	(1)	8.15	8.15	No
22511	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral.	(1)	8.05	7.58	No
22512	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; each additional cervicothoracic or lumbosacral vertebral body (list separately in addition to code for primary procedure).	(1)	4.00	4.00	No
22513	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic.	(1)	8.90	8.90	No
22514	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar.	(1)	8.24	8.24	No
22515	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; each additional thoracic or lumbar vertebral body (list separately in addition to code for primary procedure).	(1)	4.00	4.00	No
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophylectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical.	24.05	24.05	24.05	No
22858	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophylectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (list separately in addition to code for primary procedure).	(1)	8.40	8.40	No
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device.	(1)	9.03	9.03	No
29200	Strapping; thorax	0.65	0.39	0.39	No
29240	Strapping; shoulder (eg, velpeau)	0.71	0.39	0.39	No
29260	Strapping; elbow or wrist	0.55	0.39	0.39	No
29280	Strapping; hand or finger	0.51	0.39	0.39	No
29520	Strapping; hip	0.54	0.39	0.39	No
29530	Strapping; knee	0.57	0.39	0.39	No
31620	Endobronchial ultrasound (ebus) during bronchoscopic diagnostic or therapeutic intervention(s) (list separately in addition to code for primary procedure[s]).	1.40	1.50	1.40	No
33215	Repositioning of previously implanted transvenous pacemaker or implantable defibrillator (right atrial or right ventricular) electrode.	4.92	4.92	4.92	No
33216	Insertion of a single transvenous electrode, permanent pacemaker or implantable defibrillator.	5.87	5.87	5.87	No
33217	Insertion of 2 transvenous electrodes, permanent pacemaker or implantable defibrillator.	5.84	5.84	5.84	No

TABLE 25—CY 2015 INTERIM FINAL WORK RVUS FOR NEW/REVISED OR POTENTIALLY MISVALUED CODES—Continued

HCPSC Code	Long descriptor	CY 2014 WRVU	RUC/HCPAC recommended work RVU	CY 2015 work RVU	CMS time refinement
33218	Repair of single transvenous electrode, permanent pacemaker or implantable defibrillator.	6.07	6.07	6.07	No
33220	Repair of 2 transvenous electrodes for permanent pacemaker or implantable defibrillator.	6.15	6.15	6.15	No
33223	Relocation of skin pocket for implantable defibrillator	6.55	6.55	6.55	No
33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or implantable defibrillator pulse generator (including revision of pocket, removal, insertion, and/or replacement of existing generator).	9.04	9.04	9.04	No
33225	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (eg, for upgrade to dual chamber system) (list separately in addition to code for primary procedure).	8.33	8.33	8.33	No
33240	Insertion of implantable defibrillator pulse generator only; with existing single lead.	6.05	6.05	6.05	No
33241	Removal of implantable defibrillator pulse generator only	3.29	3.29	3.29	No
33243	Removal of single or dual chamber implantable defibrillator electrode(s); by thoracotomy.	23.57	23.57	23.57	No
33244	Removal of single or dual chamber implantable defibrillator electrode(s); by transvenous extraction.	13.99	13.99	13.99	No
33249	Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber.	15.17	15.17	15.17	No
33262	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; single lead system.	6.06	6.06	6.06	No
33263	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; dual lead system.	6.33	6.33	6.33	No
33270	Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed.	(1)	9.10	9.10	No
33271	Insertion of subcutaneous implantable defibrillator electrode	(1)	7.50	7.50	No
33272	Removal of subcutaneous implantable defibrillator electrode	(1)	5.42	5.42	No
33273	Repositioning of previously implanted subcutaneous implantable defibrillator electrode.	(1)	6.50	6.50	No
33418	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis.	(1)	32.25	32.25	No
33419	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; additional prosthesis(es) during same session (list separately in addition to code for primary procedure).	(1)	7.93	7.93	No
33946	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; initiation, veno-venous.	(1)	6.00	6.00	No
33947	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; initiation, veno-arterial.	(1)	6.63	6.63	No
33949	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; daily management, each day, veno-arterial.	(1)	4.60	4.60	No
33951	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), percutaneous, birth through 5 years of age (includes fluoroscopic guidance, when performed).	(1)	8.15	8.15	No
33952	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older (includes fluoroscopic guidance, when performed).	(1)	8.43	8.15	No
33953	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), open, birth through 5 years of age.	(1)	9.83	9.11	No
33954	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), open, 6 years and older.	(1)	9.43	9.11	No
33955	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; insertion of central cannula(e) by sternotomy or thoracotomy, birth through 5 years of age.	(1)	16.00	16.00	No
33956	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; insertion of central cannula(e) by sternotomy or thoracotomy, 6 years and older.	(1)	16.00	16.00	No

TABLE 25—CY 2015 INTERIM FINAL WORK RVUS FOR NEW/REVISED OR POTENTIALLY MISVALUED CODES—Continued

HCPSC Code	Long descriptor	CY 2014 WRVU	RUC/ HCPAC recommended work RVU	CY 2015 work RVU	CMS time refinement
33957	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), percutaneous, birth through 5 years of age (includes fluoroscopic guidance, when performed).	(1)	4.00	3.51	No
33958	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older (includes fluoroscopic guidance, when performed).	(1)	4.05	3.51	No
33959	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), open, birth through 5 years of age (includes fluoroscopic guidance, when performed).	(1)	4.69	4.47	No
33962	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), open, 6 years and older (includes fluoroscopic guidance, when performed).	(1)	4.73	4.47	No
33963	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; reposition of central cannula(e) by sternotomy or thoracotomy, birth through 5 years of age (includes fluoroscopic guidance, when performed).	(1)	9.00	9.00	No
33964	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; reposition central cannula(e) by sternotomy or thoracotomy, 6 years and older (includes fluoroscopic guidance, when performed).	(1)	9.50	9.50	No
33965	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), percutaneous, birth through 5 years of age.	(1)	3.51	3.51	No
33966	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older.	(1)	4.50	4.50	No
33969	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), open, birth through 5 years of age.	(1)	6.00	5.22	No
33984	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), open, 6 years and older.	(1)	6.38	5.46	No
33985	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; removal of central cannula(e) by sternotomy or thoracotomy, birth through 5 years of age.	(1)	9.89	9.89	No
33986	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; removal of central cannula(e) by sternotomy or thoracotomy, 6 years and older.	(1)	10.00	10.00	No
33987	Arterial exposure with creation of graft conduit (eg, chimney graft) to facilitate arterial perfusion for ecmo/ecls (list separately in addition to code for primary procedure).	(1)	4.04	4.04	No
33988	Insertion of left heart vent by thoracic incision (eg, sternotomy, thoracotomy) for ecmo/ecls.	(1)	15.00	15.00	No
33989	Removal of left heart vent by thoracic incision (eg, sternotomy, thoracotomy) for ecmo/ecls.	(1)	9.50	9.50	No
34839	Physician planning of a patient-specific fenestrated visceral aortic endograft requiring a minimum of 90 minutes of physician time.	(1)	C	B	N/A
34841	Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including one visceral artery endoprosthesis (superior mesenteric, celiac or renal artery).	C	C	C	N/A
34842	Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s]).	C	C	C	N/A

TABLE 25—CY 2015 INTERIM FINAL WORK RVUS FOR NEW/REVISED OR POTENTIALLY MISVALUED CODES—Continued

HCPSC Code	Long descriptor	CY 2014 WRVU	RUC/ HCPAC recommended work RVU	CY 2015 work RVU	CMS time refinement
34843	Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s]).	C	C	C	N/A
34844	Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s]).	C	C	C	N/A
34845	Endovascular repair of visceral aorta and infrarenal abdominal aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including one visceral artery endoprosthesis (superior mesenteric, celiac or renal artery).	C	C	C	N/A
34846	Endovascular repair of visceral aorta and infrarenal abdominal aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s]).	C	C	C	N/A
34847	Endovascular repair of visceral aorta and infrarenal abdominal aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s]).	C	C	C	N/A
34848	Endovascular repair of visceral aorta and infrarenal abdominal aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s]).	C	C	C	N/A
36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated.	6.72	5.30	5.30	No
36476	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; second and subsequent veins treated in a single extremity, each through separate access sites (list separately in addition to code for primary procedure).	3.38	2.65	2.65	No
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated.	6.72	5.30	5.30	No
36479	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; second and subsequent veins treated in a single extremity, each through separate access sites (list separately in addition to code for primary procedure).	3.38	2.65	2.65	No
36818	Arteriovenous anastomosis, open; by upper arm cephalic vein transposition.	11.89	13.00	12.39	No
36819	Arteriovenous anastomosis, open; by upper arm basilic vein transposition.	13.29	15.00	13.29	No
36820	Arteriovenous anastomosis, open; by forearm vein transposition	14.47	13.99	13.07	No
36821	Arteriovenous anastomosis, open; direct, any site (eg, cimino type) (separate procedure).	12.11	11.90	11.90	No

TABLE 25—CY 2015 INTERIM FINAL WORK RVUS FOR NEW/REVISED OR POTENTIALLY MISVALUED CODES—Continued

HCPSC Code	Long descriptor	CY 2014 WRVU	RUC/HCPAC recommended work RVU	CY 2015 work RVU	CMS time refinement
36825	Creation of arteriovenous fistula by other than direct arteriovenous anastomosis (separate procedure); autogenous graft.	14.17	15.93	14.17	No
36830	Creation of arteriovenous fistula by other than direct arteriovenous anastomosis (separate procedure); nonautogenous graft (eg, biological collagen, thermoplastic graft).	12.03	11.90	12.03	No
36831	Thrombectomy, open, arteriovenous fistula without revision, autogenous or nonautogenous dialysis graft (separate procedure).	8.04	11.00	11.00	Yes
36832	Revision, open, arteriovenous fistula; without thrombectomy, autogenous or nonautogenous dialysis graft (separate procedure).	10.53	13.50	13.50	Yes
36833	Revision, open, arteriovenous fistula; with thrombectomy, autogenous or nonautogenous dialysis graft (separate procedure).	11.98	14.50	14.50	Yes
37218	Transcatheter placement of intravascular stent(s), intrathoracic common carotid artery or innominate artery, open or percutaneous antegrade approach, including angioplasty, when performed, and radiological supervision and interpretation.	(1)	15.00	15.00	No
43180	Esophagoscopy, rigid, transoral with diverticulectomy of hypopharynx or cervical esophagus (eg, zenker's diverticulum), with cricopharyngeal myotomy, includes use of telescope or operating microscope and repair, when performed.	(1)	9.03	9.03	No
44381	Ileoscopy, through stoma; with transendoscopic balloon dilation	(1)	1.48	I	N/A
44384	Ileoscopy, through stoma; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed).	(1)	3.11	I	N/A
44401	Colonoscopy through stoma; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed).	(1)	4.44	I	N/A
44402	Colonoscopy through stoma; with endoscopic stent placement (including pre- and post-dilation and guide wire passage, when performed).	(1)	4.96	I	N/A
44403	Colonoscopy through stoma; with endoscopic mucosal resection	(1)	5.81	I	N/A
44404	Colonoscopy through stoma; with directed submucosal injection(s), any substance.	(1)	3.13	I	N/A
44405	Colonoscopy through stoma; with transendoscopic balloon dilation	(1)	3.33	I	N/A
44406	Colonoscopy through stoma; with endoscopic ultrasound examination, limited to the sigmoid, descending, transverse, or ascending colon and cecum and adjacent structures.	(1)	4.41	I	N/A
44407	Colonoscopy through stoma; with transendoscopic ultrasound guided intramural or transmural fine needle aspiration/biopsy(s), includes endoscopic ultrasound examination limited to the sigmoid, descending, transverse, or ascending colon and cecum and adjacent structures.	(1)	5.06	I	N/A
44408	Colonoscopy through stoma; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed.	(1)	4.24	I	N/A
45346	Sigmoidoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed).	(1)	2.97	I	N/A
45347	Sigmoidoscopy, flexible; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed).	(1)	2.98	I	N/A
45349	Sigmoidoscopy, flexible; with endoscopic mucosal resection	(1)	3.83	I	N/A
45350	Sigmoidoscopy, flexible; with band ligation(s) (eg, hemorrhoids)	(1)	1.78	I	N/A
45388	Colonoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed).	(1)	4.98	I	N/A
45389	Colonoscopy, flexible; with endoscopic stent placement (includes pre- and post-dilation and guide wire passage, when performed).	(1)	5.50	I	N/A
45390	Colonoscopy, flexible; with endoscopic mucosal resection	(1)	6.35	I	N/A
45393	Colonoscopy, flexible; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed.	(1)	4.78	I	N/A
45398	Colonoscopy, flexible; with band ligation(s) (eg, hemorrhoids)	(1)	4.30	N/A
45399	Unlisted procedure, colon	(1)	None	I	N/A
46601	Anoscopy; diagnostic, with high-resolution magnification (hra) (eg, colposcope, operating microscope) and chemical agent enhancement, including collection of specimen(s) by brushing or washing, when performed.	(1)	1.60	I	N/A
46607	Anoscopy; with high-resolution magnification (hra) (eg, colposcope, operating microscope) and chemical agent enhancement, with biopsy, single or multiple.	(1)	2.20	I	N/A
47383	Ablation, 1 or more liver tumor(s), percutaneous, cryoablation	(1)	9.13	9.13	No

TABLE 25—CY 2015 INTERIM FINAL WORK RVUS FOR NEW/REVISED OR POTENTIALLY MISVALUED CODES—Continued

HCPSC Code	Long descriptor	CY 2014 WRVU	RUC/ HCPAC recommended work RVU	CY 2015 work RVU	CMS time refinement
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant.	(1)	4.50	4.50	No
52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (list separately in addition to code for primary procedure).	(1)	1.20	1.20	No
55840	Prostatectomy, retropubic radical, with or without nerve sparing;	24.63	21.36	21.36	No
55842	Prostatectomy, retropubic radical, with or without nerve sparing; with lymph node biopsy(s) (limited pelvic lymphadenectomy).	26.49	24.16	21.36	No
55845	Prostatectomy, retropubic radical, with or without nerve sparing; with bilateral pelvic lymphadenectomy, including external iliac, hypogastric, and obturator nodes.	30.67	29.07	25.18	No
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less;.	14.70	12.29	12.29	No
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s).	16.56	14.16	14.16	No
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g;.	16.87	14.39	14.39	No
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s).	18.37	15.60	15.60	No
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less;.	15.88	13.36	13.36	No
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s).	17.69	15.00	15.00	No
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g;.	20.09	17.71	17.71	No
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s).	23.11	20.79	20.79	No
62284	Injection procedure for myelography and/or computed tomography, lumbar (other than c1–c2 and posterior fossa).	1.54	1.54	1.54	No
62302	Myelography via lumbar injection, including radiological supervision and interpretation; cervical.	(1)	2.29	2.29	No
62303	Myelography via lumbar injection, including radiological supervision and interpretation; thoracic.	(1)	2.29	2.29	No
62304	Myelography via lumbar injection, including radiological supervision and interpretation; lumbosacral.	(1)	2.25	2.25	No
62305	Myelography via lumbar injection, including radiological supervision and interpretation; 2 or more regions (eg, lumbar/thoracic, cervical/thoracic, lumbar/cervical, lumbar/thoracic/cervical).	(1)	2.35	2.35	No
64486	Transversus abdominis plane (tap) block (abdominal plane block, rectus sheath block) unilateral; by injection(s) (includes imaging guidance, when performed).	(1)	1.27	1.27	No
64487	Transversus abdominis plane (tap) block (abdominal plane block, rectus sheath block) unilateral; by continuous infusion(s) (includes imaging guidance, when performed).	(1)	1.48	1.48	No
64488	Transversus abdominis plane (tap) block (abdominal plane block, rectus sheath block) bilateral; by injections (includes imaging guidance, when performed).	(1)	1.60	1.60	No
64489	Transversus abdominis plane (tap) block (abdominal plane block, rectus sheath block) bilateral; by continuous infusions (includes imaging guidance, when performed).	(1)	1.80	1.80	No
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed.	7.15	5.44	5.44	No
66179	Aqueous shunt to extraocular equatorial plate reservoir, external approach; without graft.	(1)	14.00	14.00	No
66180	Aqueous shunt to extraocular equatorial plate reservoir, external approach; with graft.	16.30	15.00	15.00	No
66184	Revision of aqueous shunt to extraocular equatorial plate reservoir; without graft.	(1)	9.58	9.58	No
66185	Revision of aqueous shunt to extraocular equatorial plate reservoir; with graft.	9.58	10.58	10.58	No
67036	Vitrectomy, mechanical, pars plana approach;	13.32	12.13	12.13	No
67039	Vitrectomy, mechanical, pars plana approach; with focal endolaser photocoagulation.	16.74	13.20	13.20	No
67040	Vitrectomy, mechanical, pars plana approach; with endolaser panretinal photocoagulation.	19.61	14.50	14.50	No
67041	Vitrectomy, mechanical, pars plana approach; with removal of preretinal cellular membrane (eg, macular pucker).	19.25	16.33	16.33	No

TABLE 25—CY 2015 INTERIM FINAL WORK RVUS FOR NEW/REVISED OR POTENTIALLY MISVALUED CODES—Continued

HCPSC Code	Long descriptor	CY 2014 WRVU	RUC/ HCPAC recommended work RVU	CY 2015 work RVU	CMS time refinement
67042	Vitrectomy, mechanical, pars plana approach; with removal of internal limiting membrane of retina (eg, for repair of macular hole, diabetic macular edema), includes, if performed, intraocular tamponade (ie, air, gas or silicone oil).	22.38	16.33	16.33	No
67043	Vitrectomy, mechanical, pars plana approach; with removal of subretinal membrane (eg, choroidal neovascularization), includes, if performed, intraocular tamponade (ie, air, gas or silicone oil) and laser photocoagulation.	23.24	17.40	17.40	No
67255	Scleral reinforcement (separate procedure); with graft	10.17	10.17	8.38	No
70486	Computed tomography, maxillofacial area; without contrast material	1.14	0.85	0.85	No
70487	Computed tomography, maxillofacial area; with contrast material(s)	1.30	1.17	1.13	No
70488	Computed tomography, maxillofacial area; without contrast material, followed by contrast material(s) and further sections.	1.42	1.30	1.27	No
70496	Computed tomographic angiography, head, with contrast material(s), including noncontrast images, if performed, and image postprocessing.	1.75	1.75	1.75	No
70498	Computed tomographic angiography, neck, with contrast material(s), including noncontrast images, if performed, and image postprocessing.	1.75	1.75	1.75	No
71275	Computed tomographic angiography, chest (noncoronary), with contrast material(s), including noncontrast images, if performed, and image postprocessing.	1.92	1.82	1.82	No
72191	Computed tomographic angiography, pelvis, with contrast material(s), including noncontrast images, if performed, and image postprocessing.	1.81	1.81	1.81	No
72240	Myelography, cervical, radiological supervision and interpretation	0.91	0.91	0.91	No
72255	Myelography, thoracic, radiological supervision and interpretation	0.91	0.91	0.91	No
72265	Myelography, lumbosacral, radiological supervision and interpretation	0.83	0.83	0.83	No
72270	Myelography, 2 or more regions (eg, lumbar/thoracic, cervical/thoracic, lumbar/cervical, lumbar/thoracic/cervical), radiological supervision and interpretation.	1.33	1.33	1.33	No
74174	Computed tomographic angiography, abdomen and pelvis, with contrast material(s), including noncontrast images, if performed, and image postprocessing.	2.20	2.20	2.20	No
74175	Computed tomographic angiography, abdomen, with contrast material(s), including noncontrast images, if performed, and image postprocessing.	1.90	1.82	1.82	No
74230	Swallowing function, with cineradiography/videoradiography	0.53	0.53	0.53	No
76641	Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete.	(¹)	0.73	0.73	No
76642	Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; limited.	(¹)	0.68	0.68	No
76700	Ultrasound, abdominal, real time with image documentation; complete ...	0.81	0.81	0.81	No
76705	Ultrasound, abdominal, real time with image documentation; limited (eg, single organ, quadrant, follow-up).	0.59	0.59	0.59	No
76770	Ultrasound, retroperitoneal (eg, renal, aorta, nodes), real time with image documentation; complete.	0.74	0.74	0.74	No
76775	Ultrasound, retroperitoneal (eg, renal, aorta, nodes), real time with image documentation; limited.	0.58	0.58	0.58	No
76856	Ultrasound, pelvic (nonobstetric), real time with image documentation; complete.	0.69	0.69	0.69	No
76857	Ultrasound, pelvic (nonobstetric), real time with image documentation; limited or follow-up (eg, for follicles).	0.38	0.50	0.50	No
76930	Ultrasonic guidance for pericardiocentesis, imaging supervision and interpretation.	0.67	0.67	0.67	No
76932	Ultrasonic guidance for endomyocardial biopsy, imaging supervision and interpretation.	C	0.85	0.85	No
76942	Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation.	0.67	0.67	0.67	No
76948	Ultrasonic guidance for aspiration of ova, imaging supervision and interpretation.	0.38	0.92	0.92	No
77061	Digital breast tomosynthesis; unilateral	(¹)	0.70	I	N/A
77062	Digital breast tomosynthesis; bilateral	(¹)	0.90	I	N/A
77063	Screening digital breast tomosynthesis, bilateral (list separately in addition to code for primary procedure).	(¹)	0.60	0.60	No
77080	Dual-energy x-ray absorptiometry (dxa), bone density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine).	0.20	0.20	0.20	No
77085	Dual-energy x-ray absorptiometry (dxa), bone density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine), including vertebral fracture assessment.	(¹)	0.30	0.30	No

TABLE 25—CY 2015 INTERIM FINAL WORK RVUS FOR NEW/REVISED OR POTENTIALLY MISVALUED CODES—Continued

HCPSC Code	Long descriptor	CY 2014 WRVU	RUC/ HCPAC recommended work RVU	CY 2015 work RVU	CMS time refinement
77086	Vertebral fracture assessment via dual-energy x-ray absorptiometry (dxa).	(1)	0.17	0.17	No
77300	Basic radiation dosimetry calculation, central axis depth dose calculation, tdf, nsd, gap calculation, off axis factor, tissue inhomogeneity factors, calculation of non-ionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician.	0.62	0.62	0.62	No
77306	Teletherapy isodose plan; simple (1 or 2 unmodified ports directed to a single area of interest), includes basic dosimetry calculation(s).	(1)	1.40	1.40	No
77307	Teletherapy isodose plan; complex (multiple treatment areas, tangential ports, the use of wedges, blocking, rotational beam, or special beam considerations), includes basic dosimetry calculation(s).	(1)	2.90	2.90	No
77316	Brachytherapy isodose plan; simple (calculation[s] made from 1 to 4 sources, or remote afterloading brachytherapy, 1 channel), includes basic dosimetry calculation(s).	(1)	1.50	1.40	No
77317	Brachytherapy isodose plan; intermediate (calculation[s] made from 5 to 10 sources, or remote afterloading brachytherapy, 2–12 channels), includes basic dosimetry calculation(s).	(1)	1.83	1.83	No
77318	Brachytherapy isodose plan; complex (calculation[s] made from over 10 sources, or remote afterloading brachytherapy, over 12 channels), includes basic dosimetry calculation(s).	(1)	2.90	2.90	No
77385	Intensity modulated radiation treatment delivery (imrt), includes guidance and tracking, when performed; simple.	(1)	I	N/A
77386	Intensity modulated radiation treatment delivery (imrt), includes guidance and tracking, when performed; complex.	(1)	I	N/A
77387	Guidance for localization of target volume for delivery of radiation treatment delivery, includes intrafraction tracking, when performed.	(1)	0.58	I	N/A
77402	Radiation treatment delivery, >1 mev; simple	0.00	I	N/A
77407	Radiation treatment delivery, >1 mev; intermediate	0.00	I	N/A
77412	Radiation treatment delivery, >1 mev; complex	0.00	I	N/A
88341	Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure (list separately in addition to code for primary procedure).	(1)	0.65	0.42	No
88342	Immunohistochemistry or immunocytochemistry, per specimen; initial single antibody stain procedure.	I	0.70	0.70	No
88344	Immunohistochemistry or immunocytochemistry, per specimen; each multiplex antibody stain procedure.	(1)	0.77	0.77	No
88356	Morphometric analysis; nerve	3.02	2.80	2.80	No
88364	In situ hybridization (eg, fish), per specimen; each additional single probe stain procedure (list separately in addition to code for primary procedure).	(1)	0.88	0.53	No
88365	In situ hybridization (eg, fish), per specimen; initial single probe stain procedure.	1.20	0.88	0.88	No
88366	In situ hybridization (eg, fish), per specimen; each multiplex probe stain procedure.	(1)	1.24	1.24	No
88367	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; initial single probe stain procedure.	1.30	0.86	0.73	No
88368	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; initial single probe stain procedure.	1.40	0.88	0.88	No
88369	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; each additional single probe stain procedure (list separately in addition to code for primary procedure).	(1)	0.88	0.53	No
88373	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; each additional single probe stain procedure (list separately in addition to code for primary procedure).	(1)	0.86	0.43	No
88374	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; each multiplex probe stain procedure.	(1)	1.04	0.93	No
88377	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; each multiplex probe stain procedure.	(1)	1.40	1.40	No
88380	Microdissection (ie, sample preparation of microscopically identified target); laser capture.	1.56	1.14	1.14	No
88381	Microdissection (ie, sample preparation of microscopically identified target); manual.	1.18	0.53	0.53	No
91200	Liver elastography, mechanically induced shear wave (eg, vibration), without imaging, with interpretation and report.	(1)	0.30	0.30	No

TABLE 25—CY 2015 INTERIM FINAL WORK RVUS FOR NEW/REVISED OR POTENTIALLY MISVALUED CODES—Continued

HCPCS Code	Long descriptor	CY 2014 WRVU	RUC/ HCPAC recommended work RVU	CY 2015 work RVU	CMS time refinement
92145	Corneal hysteresis determination, by air impulse stimulation, unilateral or bilateral, with interpretation and report.	(1)	0.17	0.17	No
92540	Basic vestibular evaluation, includes spontaneous nystagmus test with eccentric gaze fixation nystagmus, with recording, positional nystagmus test, minimum of 4 positions, with recording, optokinetic nystagmus test, bidirectional foveal and peripheral stimulation, with recording, and oscillating tracking test, with recording.	1.50	1.50	1.50	No
92541	Spontaneous nystagmus test, including gaze and fixation nystagmus, with recording.	0.40	0.40	0.40	No
92542	Positional nystagmus test, minimum of 4 positions, with recording	0.33	0.48	0.48	No
92543	Caloric vestibular test, each irrigation (binaural, bithermal stimulation constitutes 4 tests), with recording.	0.10	0.35	0.10	No
92544	Optokinetic nystagmus test, bidirectional, foveal or peripheral stimulation, with recording.	0.26	0.27	0.27	No
92545	Oscillating tracking test, with recording	0.23	0.27	0.27	No
93260	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; implantable subcutaneous lead defibrillator system.	(1)	0.85	0.85	No
93261	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable subcutaneous lead defibrillator system.	(1)	0.74	0.74	No
93282	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; single lead transvenous implantable defibrillator system.	0.85	0.85	0.85	No
93283	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; dual lead transvenous implantable defibrillator system.	1.15	1.15	1.15	No
93284	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead transvenous implantable defibrillator system.	1.25	1.25	1.25	No
93287	Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead implantable defibrillator system.	0.45	0.45	0.45	No
93289	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead transvenous implantable defibrillator system, including analysis of heart rhythm derived data elements.	0.92	0.92	0.92	No
93312	Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); including probe placement, image acquisition, interpretation and report.	2.20	3.18	2.55	No
93313	Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); placement of transesophageal probe only.	0.95	1.00	0.51	No
93314	Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); image acquisition, interpretation and report only.	1.25	2.80	2.10	Yes
93315	Transesophageal echocardiography for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report.	C	3.29	2.94	No
93316	Transesophageal echocardiography for congenital cardiac anomalies; placement of transesophageal probe only.	0.95	1.50	0.85	No
93317	Transesophageal echocardiography for congenital cardiac anomalies; image acquisition, interpretation and report only.	C	3.00	2.09	Yes

TABLE 25—CY 2015 INTERIM FINAL WORK RVUS FOR NEW/REVISED OR POTENTIALLY MISVALUED CODES—Continued

HCPSC Code	Long descriptor	CY 2014 WRVU	RUC/ HCPAC recommended work RVU	CY 2015 work RVU	CMS time refinement
93318	Echocardiography, transesophageal (tee) for monitoring purposes, including probe placement, real time 2-dimensional image acquisition and interpretation leading to ongoing (continuous) assessment of (dynamically changing) cardiac pumping function and to therapeutic measures on an immediate time basis.	C	2.40	2.40	No
93320	Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (list separately in addition to codes for echocardiographic imaging); complete.	0.38	0.38	0.38	No
93321	Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (list separately in addition to codes for echocardiographic imaging); follow-up or limited study (list separately in addition to codes for echocardiographic imaging).	0.15	0.15	0.15	No
93325	Doppler echocardiography color flow velocity mapping (list separately in addition to codes for echocardiography).	0.07	0.07	0.07	No
93355	Echocardiography, transesophageal (tee) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (eg, tavr, transcatheter pulmonary valve replacement, mitral valve repair, paravalvular regurgitation repair, left atrial appendage occlusion/closure, ventricular septal defect closure) (peri- and intra-procedural), real-time image acquisition and documentation, guidance with quantitative measurements, probe manipulation, interpretation, and report, including diagnostic transesophageal echocardiography and, when performed, administration of ultrasound contrast, doppler, color flow, and 3d.	(1)	4.66	4.66	No
93644	Electrophysiologic evaluation of subcutaneous implantable defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters).	(1)	3.65	3.29	No
93880	Duplex scan of extracranial arteries; complete bilateral study	0.60	0.80	0.80	No
93882	Duplex scan of extracranial arteries; unilateral or limited study	0.40	0.50	0.50	No
93886	Transcranial doppler study of the intracranial arteries; complete study	0.94	1.00	0.91	No
93888	Transcranial doppler study of the intracranial arteries; limited study	0.62	0.70	0.50	No
93895	Quantitative carotid intima media thickness and carotid atheroma evaluation, bilateral.	(1)	0.55	N	No
93925	Duplex scan of lower extremity arteries or arterial bypass grafts; complete bilateral study.	0.80	0.80	0.80	No
93926	Duplex scan of lower extremity arteries or arterial bypass grafts; unilateral or limited study.	0.50	0.60	0.50	No
93930	Duplex scan of upper extremity arteries or arterial bypass grafts; complete bilateral study.	0.46	0.80	0.80	No
93931	Duplex scan of upper extremity arteries or arterial bypass grafts; unilateral or limited study.	0.31	0.50	0.50	No
93970	Duplex scan of extremity veins including responses to compression and other maneuvers; complete bilateral study.	0.70	0.70	0.70	No
93971	Duplex scan of extremity veins including responses to compression and other maneuvers; unilateral or limited study.	0.45	0.45	0.45	No
93975	Duplex scan of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; complete study.	1.80	1.30	1.16	No
93976	Duplex scan of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; limited study.	1.21	1.00	0.80	No
93978	Duplex scan of aorta, inferior vena cava, iliac vasculature, or bypass grafts; complete study.	0.65	0.97	0.80	No
93979	Duplex scan of aorta, inferior vena cava, iliac vasculature, or bypass grafts; unilateral or limited study.	0.44	0.70	0.50	No
93990	Duplex scan of hemodialysis access (including arterial inflow, body of access and venous outflow).	0.25	0.60	0.50	No
95971	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming.	0.78	0.78	0.78	No

TABLE 25—CY 2015 INTERIM FINAL WORK RVUS FOR NEW/REVISED OR POTENTIALLY MISVALUED CODES—Continued

HCPCS Code	Long descriptor	CY 2014 WRVU	RUC/HCPAC recommended work RVU	CY 2015 work RVU	CMS time refinement
95972	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, up to 1 hour.	1.50	0.90	0.80	No
95973	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (list separately in addition to code for primary procedure).	0.92	NA	0.49	No
97605	Negative pressure wound therapy (eg, vacuum assisted drainage collection), utilizing durable medical equipment (dme), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters.	0.55	0.55	0.55	No
97606	Negative pressure wound therapy (eg, vacuum assisted drainage collection), utilizing durable medical equipment (dme), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters.	0.60	0.60	0.60	No
97607	Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters.	(1)	0.41	C	
97608	Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters.	(1)	0.46	C	Yes
97610	Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day.	C	0.35	0.35	No
99183	Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session.	2.34	2.11	2.11	No
99184	Initiation of selective head or total body hypothermia in the critically ill neonate, includes appropriate patient selection by review of clinical, imaging and laboratory data, confirmation of esophageal temperature probe location, evaluation of amplitude eeg, supervision of controlled hypothermia, and assessment of patient tolerance of cooling.	(1)	4.50	4.50	No
99188	Application of topical fluoride varnish by a physician or other qualified health care professional.	(1)	0.20	N	N/A
99487	Complex chronic care management services, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; establishment or substantial revision of a comprehensive care plan; moderate or high complexity medical decision making; 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month.	1.00	1.00	B	N/A
99497	Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; first 30 minutes, face-to-face with the patient, family member(s), and/or surrogate.	(1)	1.50	I	N/A

TABLE 25—CY 2015 INTERIM FINAL WORK RVUS FOR NEW/REVISED OR POTENTIALLY MISVALUED CODES—Continued

HCPSC Code	Long descriptor	CY 2014 WRVU	RUC/HCPAC recommended work RVU	CY 2015 work RVU	CMS time refinement
99498	Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; each additional 30 minutes (list separately in addition to code for primary procedure).	(¹)	1.40	I	N/A
G0279 ...	Diagnostic digital breast tomosynthesis, unilateral or bilateral (list separately in addition to G0204 or G0206).	(¹)	N/A	0.60	N/A

¹ New.

i. Code Specific Issues

(1) Internal Fixation of Rib Fracture (CPT Codes 21811, 21812 and 21813)

For CY 2015, the CPT Editorial Panel deleted CPT code 21810 (Treatment of rib fracture requiring external fixation (flail chest)) and replaced it with three CPT codes 21811, 21812 and 21813, to report internal fixation of rib fracture. The RUC recommended valuing these three codes as 90-day global services. For the reasons we articulate in section II.B.4 of this final rule with comment period about the difficulties in accurately valuing codes as 90-day global services, we believe that the valuation of these codes should be as 0-day global services. In addition, we believe this is particularly appropriate for these codes because the number of RUC-recommended inpatient and outpatient visits included in the postservice time seems higher than would likely occur. The vignette for CPT code 21811 describes an elderly patient who falls and experiences three rib fractures that require internal fixation. The seven visits included in the postservice time for this code seem high since the vignette does not describe a very ill patient. The vignettes for CPT codes 21812 and 21813 describe patients experiencing significant rib fractures in car accidents that require internal fixation. We believe that in these scenarios, injuries beyond rib fractures are likely, and as a result, we believe it is likely that multiple practitioners would be involved in providing post-operative care. If other practitioners would furnish care in the post-surgery period, we believe the ten and thirteen postservice visits included in CPT codes 21812 and 21813 would likely not occur. By valuing these codes as 0-day globals, we do not need to address these issues because the surgeon will be able to bill separately for the postoperative services that are furnished after the day of the procedure.

To value these services as 0-day global codes, we subtracted the work RVUs related to the postoperative services from the total work RVU. We are establishing CY 2015 interim work RVUs of 10.79 for CPT code 21811, of 13.00 for CPT code 21812, and of 17.61 for CPT code 21813. We also refined the RUC recommended time by subtracting the time associated with the postoperative visits. By removing the work and time associated with visits in the postoperative period, the remaining work and time reflect the work and time of services furnished on the day of surgery.

(2) Percutaneous Vertebroplasty and Augmentation (CPT Codes 22510, 22511, 22512, 22513, 22514 and 22515)

For CY 2015, the CPT Editorial Panel replaced the eight existing percutaneous vertebroplasty with six new codes, CPT codes 22510–22515, which include the percutaneous vertebroplasty and the image guidance together. We are establishing the RUC-recommended work values as interim final for CY 2015 for all of the codes in this family except CPT code 22511.

Unlike other codes in this family for which the RUC-recommended work RVU was based on the 25th percentile in the survey, the RUC established its recommended work value for CPT code 22511 by crosswalking this service to CPT code 39400 (Mediastinoscopy, includes biopsy(ies), when performed), which has a work RVU of 8.05. Because the level of work performed by a physician in the two services differs, we do not agree that this crosswalk is appropriate. Instead, we believe a more appropriate analogy is found in the difference between the work values for the predecessor codes for CPT codes 22510 and 22511, CPT codes 22520 (Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection; thoracic) and 22521 (Percutaneous vertebroplasty (bone

biopsy included when performed), 1 vertebral body, unilateral or bilateral injection; thoracic; lumbar). Accordingly, we are applying the difference in the current work RVUs for CPT codes 22520 and 22521 to the work RVU that we are establishing for CPT code 22510. We believe this increment establishes the appropriate rank order in this family and thus are assigning an interim final work RVU of 7.58 for CPT code 22511, which is 0.57 work RVUs lower than the CY 2015 work RVU for CPT code 22510.

(3) Endobronchial Ultrasound (EBUS) (CPT Code 31620)

For CY 2015, the RUC reviewed CPT code 31620 because it was identified through the High Volume Growth Services, which are those services for which Medicare utilization increased by at least 100 percent from 2006 to 2011. CPT code 31620 is an add-on code to CPT code 31629 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s), trachea, main stem and/or lobar bronchus(i)).

Medicare data show that 82 percent of the time when EBUS is billed it is billed with CPT code 31629. Given this relationship, we believe that CPT code 31620 should be bundled with CPT code 31629. The specialty societies maintain that EBUS is distinct from bronchoscopy with biopsy because the intraservice work of EBUS occurs between the two components of the base code, bronchoscopy and biopsy. However, based upon the discussion at the RUC meeting, we believe that the biopsy actually occurs during the EBUS and the biopsy is actually performed through the EBUS scope. Thus, we do not believe the EBUS code descriptor accurately describes the service nor is it possible to accurately value this service when the descriptor is inaccurate. Therefore, for CY 2015 we are maintaining the CY 2014 work RVU for

CPT code 31620. We understand that the RUC will review this code for CY 2016.

(4) Extracorporeal Membrane Oxygenation (ECMO)/Extracorporeal Life Support (ECLS) (CPT Codes 33946, 33947, 33948, 33949, 33951–33959, 33962–33966, 33969, 33984–33989)

In the CY 2014 PFS final rule with comment period, CPT codes 33960 (Prolonged extracorporeal circulation for cardiopulmonary insufficiency; initial day) and 33961 (Prolonged extracorporeal circulation for cardiopulmonary insufficiency; each subsequent day) were identified as potentially misvalued codes. Specifically, the services were originally valued when they were primarily provided to premature neonates; but the services are now typically used in treating adults with severe influenza, pneumonia, and respiratory distress syndrome. For CY 2015, CPT codes 33960 and 33961 were deleted and replaced with 25 new codes to describe this treatment. We are assigning the RUC-recommended work values as interim final for CY 2015 for all of the codes in this family except CPT codes 33952, 33953, 33954, 33957, 33958 and 33959, 33962, 33969, and 33984.

We accepted the RUC-recommended work RVU of 8.15 for CPT code 33951, which describes an ECMO peripheral cannula(e) insertion for individuals up to 5 years of age. The RUC recommended a work RVU of 8.43 for CPT code 33952, which describes the same procedure for individuals 6 years and older. We do not believe this difference in the age of the patient increases the work of the service from the younger patient. The fact that the RUC-recommended intraservice time is identical for both codes supports our view that the work RVU should be the same for both codes. Therefore, for CY 2015, we are establishing an interim final work RVUs of 8.15 for CPT code 33952, the same as we established for CPT 33951 based upon the RUC-recommendation for the younger patient.

The RUC recommended work RVUs of 9.83 and 9.43 for CPT codes 33953 and 33954, respectively. For the same reasons discussed above, we are establishing the same work values for the code for treatment of patients from birth through 5 years of age and the code for treatment of patients 6 years and older. To determine the value for these codes, we adjusted the work RVU of the equivalent percutaneous codes, CPT code 33951 (Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS)

provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), percutaneous, birth through 5 years of age (includes fluoroscopic guidance, when performed)) and CPT code 33952 (Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), open birth, through 5 years of age) and 33954 (Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), open, 6 years and older). To measure the difference in work between these two sets of codes we applied the 0.96 RVU differential between the percutaneous arterial CPT code 33620 (Application of right and left pulmonary artery bands (for example, hybrid approach stage 1)) and the open arterial CPT code 36625 (Arterial catheterization or cannulation for sampling, monitoring or transfusion (separate procedure); cutdown) codes. This measure allows us to establish the difference in work between the sets of codes based upon the difference in intensity. Accordingly, we are assigning an interim final work RVU to CPT codes 33953 and 33954 of 9.11.

Unlike other codes in this family for which the RUC-recommended work value was based upon the 25th percentile of the survey, for CPT codes 33957 and 33958 the RUC recommended a work RVU of 4.00 and 4.05, respectively, based upon the survey median. We believe that, like other services in this family, these codes should be valued based upon the 25th percentile values of the survey because those values best describe the work involved in these procedures and results in the appropriate relativity amongst the codes in the family. Therefore, for CY 2015 we are assigning an interim final work RVU of 3.51 for CPT codes 33957 and 33958.

We believe the RUC-recommended work RVUs of 4.69 and 4.73 for CPT codes 33959 and 33962 respectively, overstate the work involved in the services. As we discussed above for CPT codes 33953 and 33954, we believe the differential between the percutaneous arterial and open arterial CPT codes more appropriately reflects the work

involved in these services. Accordingly we are establishing a CY 2015 interim final work RVU of 4.47 for CPT codes 33959 and 33962.

After researching comparable codes, we believe the RUC-recommended work RVUs of 6.00 and 6.38 for CPT codes 33969 and 33984, respectively, overstates the work involved in the procedures. For the same reasons and following the same valuation methodology utilized above, we added the differential between the percutaneous arterial and arterial cutdown codes, 0.96 RVU, to the CY 2015 interim final work RVU of 4.50 for CPT code 33966, which is the percutaneous counterpart of CPT code 33984. This results in a work RVU of 5.46 for CPT code 33984. Because CPT code 33969 has 2 minutes less intraservice time than CPT code 33984 (Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), open, 6 years and older), we adjusted the work RVU of CPT code 33984 for the decrease in time to get a work RVU of 5.22 for CPT code 33969 (Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), open, birth through 5 years of age). Therefore, for CY 2015 we are establishing an interim final work RVU of 5.46 to CPT code 33984 and 5.22 to CPT code 33969.

(5) Fenestrated Endovascular Repair (FEVAR) Endograft Planning (CPT Code 34839)

For CY 2015, CPT code 34839 was created to report the planning that occurs prior to the work included in the global period for a FEVAR. The RUC recommended that we contractor price this service as the RUC survey response rate was too low to provide the basis for an appropriate valuation. In general, we prefer that planning be bundled with the underlying service, and we have no reason to believe bundling is not appropriate in this case. Accordingly, we are assigning a PFS procedure status indicator of B (Bundled Code) to CPT code 34839.

(6) AV Anastomosis (CPT Codes 36818, 36819, 36820, 36821, 36825, 36830, 36831, 36832, and 36833)

In the CY 2013 PFS final rule with comment period, the AV anastomosis family of services were determined to be potentially misvalued due to rank order anomalies, including CPT codes 36818–36821 and CPT codes 36825–36830. The RUC recommendations that we received

in response also included CPT codes 36831–36833. We are assigning the RUC-recommended work RVUs as CY 2015 interim final values for CPT codes 36821, 36831, 36832 and 36833. For CPT code 36831, 36832, and 36833, we are refining to remove the additional 10 minutes of preservice evaluation time. The RUC added 10 minutes of additional pre-service time to these codes for determining the best source of access. These three codes are revision/repair codes and as such do not need the additional time to determine the access source. For CPT code 36818, the RUC recommended an approximately 12 percent increase in work RVU but a total time increase of approximately 4.2 percent. We are assigning a CY 2015 interim final work RVU of 12.39, which reflects a 4.2 percent increase from the current value based upon the increase in total time.

For CPT code 36819, the RUC-recommended intraservice and total times are only minimally different than the current times. Even though the intraservice and total times decreased minimally, the RUC increased the work RVU. We believe that the small decrease in total time, 2 percent, suggest that the current work RUV is appropriate. Therefore, we are assigning a CY 2015 interim final work RVU of 13.29, which is the current work value.

The RUC recommended a work value of 13.99 for CPT code 36820. The RUC recommended that the postservice time of CPT code 36820 be reduced by removing visits. Specifically, a CPT code 99231 and one-half of a CPT code 99238 were removed from the service, which would equal 1.40 RVU. We do not believe that this reduction was accounted for in the RUC-recommended work RVU. To account for this reduction in visits, we are establishing a CY 2015 interim final work RVU of 13.07 for CPT 36820 which reflects a 1.40 work RVU reduction in the current work RVU.

For CPT code 36825, the RUC-recommended intraservice and total times are only minimally different than the current times. However, the RUC increased the work RVU. We do not

believe the work RVU should be increased without corresponding time changes. Therefore, we believe the appropriate CY 2015 interim final work RVU is the current work value of 14.17. For CPT code 36830, the RUC-recommended intraservice and total times are only minimally different than the current times. However, the RUC decreased the work RVU. We do not believe the work RVU should be decreased without corresponding time changes. Therefore, we are establishing a CY 2015 interim final work RVU of 12.03, which is equal to the current work RVU.

Furthermore, we refined the total time values as follows: 238 minutes for CPT code 36831, 266 minutes for CPT code 36832, and 296 minutes for CPT code 36833.

(7) Ileoscopy, Pouchoscopy, Colonoscopy through Stoma, Flexible Sigmoidoscopy and Colonoscopy (CPT Codes 44380, 44381, 44382, 44383, 44384, 44385, 44386, 44388, 44389, 44390, 44391, 44392, 44393, 44394, 44397, 44401, 44402, 44403, 44404, 44405, 44406, 44407, 44408, 44799, 45330, 45331, 45332, 45333, 45334, 45335, 45337, 45338, 45346, 45340, 45341, 45342, 45345, 45347, 45349, 45350, 45378, 45379, 45380, 45381, 45382, 45383, 45388, 45384, 45385, 45386, 45387, 45389, 45390, 45391, 45392, 45393, 45398, 45399, 0226T, 46601, 0227T, and 46607 and HCPCS Codes G6018, G6019, G6020, G6021, G6022, G6023, G6024, G6025, G6027, G6028)

CPT revised the lower gastrointestinal endoscopy code set for CY 2015 following identification of some of the codes as potentially misvalued and the affected specialty society's contention that this code set did not allow for accurate reporting of services based upon the current practice. The RUC subsequently provided recommendations to CMS for valuing these services. In comments on the proposed rule, stakeholders noted our proposal to begin including proposed values for new, revised and potentially misvalued codes in the proposed rule.

Commenters suggested that, rather than implementing this new process in CY 2016, we should implement it immediately and thus defer the valuation of the new GI code set until CY 2016. They indicated that the opportunity to comment prior to implementation of the new values was important for these codes, many of which have high utilization. In addition, in this final rule with comment period we discuss the need to modify how moderate sedation is reported and valued. Since the valuation of most codes in this code set includes moderate sedation, stakeholders suggested that we revalue these codes in conjunction with any changes in reporting and valuation of moderate sedation.

We agree with the commenters. In light of the substantial nature of this code revision and its relationship to the policies on moderate sedation, we are delaying revaluation of these codes until CY 2016 when we will be able to include proposals in the proposed rule for their valuation, along with consideration of policies for moderate sedation. Accordingly for CY 2015, we are maintaining the inputs for the lower gastrointestinal endoscopy codes at the CY 2014 levels. (Note: Due to budget neutrality adjustments and other system-wide changes, the payment rates may change.) Since the code set is changing for CY 2015, including the deletion of some of the CY 2014 codes, we are creating G-codes as necessary to allow practitioners to report services to CMS in the same way in CY 2015 that they did in CY 2014 and to maintain payment under the PFS based on the same inputs. All payment policies applicable to the CY 2014 CPT codes will apply to the replacement G-codes. The new and revised CY 2015 CPT codes for lower gastrointestinal endoscopy that will not be recognized by Medicare for CY 2015 are denoted with an "I" (Not valid for Medicare purposes) in Table 26. The chart below lists the G-codes that we are creating and the CY 2014 CPT codes that they are replacing.

TABLE 26—LOWER GASTROINTESTINAL ENDOSCOPY G-CODES REPLACING CY 2015 CPT CODES

CY 2014 CPT code ¹	CY 2015 HCPCS code	Long descriptor
44383	G6018	Ileoscopy, through stoma; with transendoscopic stent placement (includes predilation).
44393	G6019	Colonoscopy through stoma; with ablation of tumor(s), polp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique.
44397	G6020	Colonoscopy through stoma; with transendoscopic stent placement (includes predilation).
44799	G6021	Unlisted procedure, intestine.
45339	G6022	Sigmoidoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesions(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique.

TABLE 26—LOWER GASTROINTESTINAL ENDOSCOPY G-CODES REPLACING CY 2015 CPT CODES—Continued

CY 2014 CPT code ¹	CY 2015 HCPCS code	Long descriptor
45345	G6023	Sigmoidoscopy, flexible; with transendoscopic stent placement (includes predilation).
45383	G6024	Colonoscopy, flexible, proximal to splenic flexure; with ablation of tumor(s), polyp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique.
45387	G6025	Colonoscopy, flexible, proximal to splenic flexure; with transendoscopic stent placement (includes predilation).
0226T	G6027	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed.
0227T	G6028	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies).

¹ This chart only contains CY 2014 codes for which a HCPCS code is being used for CY 2015. Addendum B contains a complete list of CPT and HCPCS codes being recognized by Medicare under the PFS for CY 2015.

(8) Prostatectomy (CPT Codes 55842 and 55845)

In the CY 2014 PFS final rule with comment period, we finalized CPT codes 55842 and 55845 as potentially misvalued codes. For CY 2015, the RUC provided recommendations for these services of 29.07 and 24.16, respectively. We disagreed with the RUC-recommended crosswalk for CPT code 55842. To value CPT code 55842, we are crosswalking it to CPT code 55840 (Prostatectomy, retropubic radical, with or without nerve sparing) due to their identical times. Therefore, we are establishing an interim final work RVU of 21.36.

For CPT code 55845, we are establishing a work RVU of 25.18 based upon the 25th percentile of the survey. This work RVU results in an 18 percent decrease from the current work RVU, which we believe reflects the changes since the last valuation, based upon a 20 percent decrease in intraservice time and the 29 percent decrease in total time.

(9) Aqueous Shunt (CPT Code 66179, 66180, 66184, 66185, and 67255)

After identifying CPT code 66180 through the Harvard-Valued Annual Allowed Charges Greater than \$10 million screen, the RUC recommended work RVUs for the aqueous shunt family for CY 2015. We are establishing the RUC-recommended work RVUs as interim final for all codes in this family except CPT code 67255. The RUC recommended maintaining the CY 2014 work RVU of 10.17 for CPT 67255. However, we believe maintaining this value would be inconsistent with the RUC-recommended decreases in total time for the service. As a result, we reduced the work RVU by the same percentage that the RUC recommended a reduction in total time, which results in a CY 2015 interim final work RVU of 8.38 for CPT code 67255.

(10) Computed Tomography (CT)—Maxillofacial (CPT Codes 70486, 70487 and 70488)

The RUC's Relativity Assessment Workgroup identified CPT code 70486 for review through the CMS/Other Source—Utilization over 250,000 screen. The involved specialty societies expanded the survey to include CPT codes 70487 and 70488, all of which involve maxillofacial CTs. We are establishing the RUC-recommended work RVU of 0.85 as the CY 2015 interim final value for CPT code 70486, which is without contrast material. The RUC established this recommendation by crosswalking this code to the equivalent code in the CT for the head or brain, CPT code 70450 (Computed tomography, head or brain without contrast). We agree with that method and in order to maintain rank order within and across CT families, we crosswalked CPT code 70487, which is with contrast material(s), to the CPT code 70460, which is the equivalent code in the head or brain family and CPT code 70488, which is without contrast materials followed by contrast material(s) and further sections to CPT code 70470, which is the equivalent code in the head or brain family. Therefore, for CY 2015 we are establishing interim final work RVUs of 1.13 for CPT code 70487 and 1.27 for CPT code 70488.

(11) Breast Ultrasound (CPT Codes 76641 and 76642)

For CY 2015, the CPT Editorial Panel replaced CPT code 76645 (Ultrasound, breast(s) (unilateral or bilateral), real time with image documentation) with two codes, CPT codes 76641 (Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete) and 76642 (Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; limited). The difference between the new codes is that one is for complete

breast ultrasound procedures and the other is for limited. We are assigning the RUC-recommended work RVUs of 0.73 and 0.68 to CPT codes 76641 and 76642, respectively, as interim final. One difference between the predecessor code and the new ones is that while the predecessor code was used to report unilateral or bilateral breast ultrasounds, the new codes are unilateral ones. To appropriately adjust payment when bilateral procedures are furnished under the PFS, payments are adjusted to 150 percent of the unilateral payment when a service has a bilateral payment indicator assigned. We are assigning a bilateral payment indicator to these codes.

(12) Radiation Therapy Codes (CPT Codes 76950, 77014, 77421, 77387, 77401, 77402, 77403, 77404, 77406, 77407, 77408, 77409, 77411, 77412, 77413, 77414, 77416, 77418, 77385, 77386, 0073T, and 0197T and HCPCS Codes G6001, G6002, G6003, G6004, G6005, G6006, G6007, G6008, G6009, G6010, G6011, G6012, G6013, G6014, G6015, G6016 and G6017)

CPT revised the radiation therapy code set for CY 2015 following identification of some of the codes as potentially misvalued and the affected specialty society's contention that the provision of radiation therapy could not be accurately reported under the existing code set. The RUC subsequently provided recommendations to CMS for valuing these services. Some stakeholders approached CMS with concerns about these codes being revalued as interim final in the final rule with comment period, noting that these codes account for the vast majority of Medicare payment for radiation therapy centers. They noted our proposal to begin including proposals to value new, revised and potentially misvalued codes in the proposed rule, and suggested that these code valuations should be delayed to CY 2016 so that they could be addressed under this new process. This would provide affected

stakeholders the opportunity to comment prior to the valuations being effective. They also noted that since they do not participate in the RUC, they did not have the opportunity to provide input to the recommendations nor will they have information about the RUC recommendations until CMS makes this information available in the final rule with comment period.

In response to comments and in light of the substantial nature of this code revision, we are delaying revaluation of these codes until CY 2016. The coding changes for CY 2015 involve significant changes in how radiation therapy services and associated image guidance are reported. There is substantial work to be done to assure the new valuations for these codes accurately reflect the coding changes. Accordingly we are delaying the use of the revised radiation therapy code set until CY 2016 when we will be able to include proposals in the proposed rule for their valuation. We are maintaining the inputs for radiation

therapy codes at the CY 2014 levels. (Note: Due to budget neutrality adjustments and other system-wide changes, the payment rates may change.) Since the code set has changed and some of the CY 2014 codes are being deleted, we are creating G-codes as necessary to allow practitioners to continue to report services to CMS in CY 2015 as they did in CY 2014 and for payments to be made in the same way. All payment policies applicable to the CY 2014 CPT codes will apply to the replacement G-codes. The new and revised CY 2015 CPT codes that will not be recognized by Medicare for CY 2015 are denoted with an “I” (Not valid for Medicare purposes) on Table 27. The chart below lists the G-codes that we are creating and the CY 2014 CPT codes that they are replacing.

Additionally, we would like to note that changes to the prefatory text modify the services that are appropriately billed with CPT code 77401, which is used to report superficial radiation therapy.

This change effectively means that CPT code 77401 is now bundled with many other procedures supporting superficial radiation therapy. However, the RUC did not review superficial radiation therapy procedures, and therefore, did not assess whether changes in its valuation were appropriate in light of this bundling. Stakeholders have suggested to us that the change to the prefatory text prohibits them from billing for codes that were previously frequently billed in addition to this code and as a result there will be a significant reduction in their payments.” We are interested in information on whether the new code set combined with modifications in prefatory text allows for appropriate reporting of the services associated with superficial radiation and whether the payment continues to reflect the relative resources required to furnish superficial radiation therapy services.

TABLE 27—RADIATION THERAPY G-CODES REPLACING CY 2015 CPT CODES

CY 2014 CPT code ²	CY 2015 HCPCS code	Long descriptor
76950	G6001	Ultrasonic guidance for placement of radiation therapy fields.
77421	G6002	Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy.
77402	G6003	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: up to 5MeV.
77403	G6004	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: 6–10MeV.
77404	G6005	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: 11–19MeV.
77406	G6006	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: 20 MeV or greater.
77407	G6007	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks; up to 5MeV.
77408	G6008	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks; 6–10MeV.
77409	G6009	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks; 11–19MeV.
77411	G6010	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks; 20 MeV or greater.
77412	G6011	Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; up to 5MeV.
77413	G6012	Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 6–10MeV.
77414	G6013	Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 11–19MeV.
77416	G6014	Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 20MeV or greater.
77418	G6015	Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session.
0073T	G6016	Compensator-based beam modulation treatment delivery of inverse planned treatment using 3 or more high resolution (milled or cast) compensator, convergent beam modulated fields, per treatment session.
0197T	G6017	Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy (eg, 3D positional tracking, gating, 3D surface tracking), each fraction of treatment.

(13) Breast Tomosynthesis (CPT codes 77061, 77062, and 77063)

For CY 2015, the CPT Editorial Panel created three codes to describe digital breast tomosynthesis services: 77061 (Digital breast tomosynthesis; unilateral), 77062 (Digital breast tomosynthesis; bilateral) and 77063 (Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure) and we received RUC recommendations for these codes. Currently, these services are reported to Medicare using G0202, G0204, and G0206, which describe the equivalent procedures using any digital technology (2-D or 3-D). In addition, film mammography is reported to Medicare using CPT codes 77055, 77056 and 77057).

In the proposed rule, based upon our belief that digital mammography is now typical, we proposed to replace the G-codes that currently describe all digital mammography services under Medicare with the CPT codes, to value the CPT codes for CY 2015 based upon the current G-code values, and to include the CPT codes on the potentially misvalued code list since the resources involved in furnishing these services had not been evaluated in more than a decade. Having reassessed the proposal in light of the new codes and RUC recommendations for tomosynthesis and the comments received upon our proposal, we are finalizing a modified proposal. For a discussion of our proposal, a summary of the comments we received, and our policy for CY 2015, see section II.B.4.

With regard to screening mammography, the CPT coding system now has an add-on CPT code for tomosynthesis. This coding scheme is consistent with the FDA requiring a 2-D mammography when tomosynthesis is used for screening purposes. Accordingly, we will recognize CPT code 77063 to be reported, when tomosynthesis is used in addition to 2-D mammography. Since CPT code 77063 is an add-on code, and does not have an equivalent CY 2014 code, we believe it is appropriate to value it on an interim final basis in advance of receiving the RUC recommendations for other mammography services. We are assigning it a CY 2015 interim final work RVU of 0.60 as recommended by the RUC.

Whenever feasible, it is our strong preference to value entire families

together in order to avoid rank order anomalies. In this final rule with comment period, we are including the codes for digital mammography on the potentially misvalued code list, which currently includes tomosynthesis as well as 2-D mammography. Accordingly, we will wait to value the new diagnostic mammography tomosynthesis codes until we have received recommendations from the RUC for all mammography services. In the interim, we are assigning a PFS indicator of "I" to 77061 and 77062. Those furnishing diagnostic mammography using tomosynthesis will continue to report G0204 and G0206 as appropriate. In addition, we are creating a new code, G-2079 (Diagnostic digital breast tomosynthesis, unilateral or bilateral (List separately in addition to G0204 or G0206)) as an add-on code that should be reported in addition to the relevant 2-D diagnostic mammography G-code to recognize the additional resources involved in furnishing diagnostic breast tomosynthesis. We will assign it the same inputs as CPT code 77063 because we believe it describes a similar service.

(14) Isodose Calculation with Isodose Planning Bundle (CPT Code 77316)

For CY 2015, the CPT Editorial Panel replaced six CPT codes (77305, 77310, 77315, 77326, 77327, and 77328) with five new CPT codes to bundle basic dosimetry calculation(s) with teletherapy and brachytherapy isodose planning. We are establishing the RUC-recommended work RVUs for CY 2015 for all of the codes in this family except CPT code 77316. We disagree with the RUC-recommended crosswalk for this service because we do not believe it is an appropriate match in work. The RUC crosswalked CPT code 77318 to CPT code 77307, both of which are complex isodose planning codes in the same family. We believe that the RUC should have crosswalked CPT code 77316, a simple isodose planning code, to the corresponding simple isodose planning code in the same family, CPT code 77306. Therefore, for CY 2015 we are establishing an interim final work RVU of 1.40 for CPT code 77316.

(15) Immunohistochemistry (CPT codes 88341, 88342, and 88344; HCPCS codes G0461 and G0462)

In the CY 2014 PFS final rule with comment period (78 FR 74341), we assigned a status indicator of I (Not valid for Medicare purposes) to CPT codes 88341, 88342, and 88343 and instead created two G-codes, G0461 and G0462, to report immunohistochemistry services. We did this in part to avoid

creating incentives for overutilization. For CY 2015, the CPT coding was revised with the creation of two new CPT codes, 88341 and 88344, the revision of CPT code 88342 and the deletion of CPT code 88343. We believe that the revised coding structure addresses the concerns that we had with the CY 2014 coding regarding the creation of incentives and overutilization. Accordingly, we are deleting the G-codes and assigning interim final values for these CPT codes for CY 2015. We are establishing the RUC-recommended work RVUs as interim final for CY 2015 for CPT codes 88342 and 88344.

In the past for similar procedures in this family, the RUC recommended a work RVU for the add-on code that was 60 percent of the base code. For example, the RUC-recommended work RVU for CPT code 88334 (Pathology consultation during surgery; cytologic examination (for example, touch prep, squash prep), each additional site (List separately in addition to code for primary procedure)) is 60 percent of the work RVU of the base CPT code 88333 (Pathology consultation during surgery; cytologic examination (for example, touch prep, squash prep), initial site). Similarly, the RUC-recommended work RVU for CPT code 88177 (Cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy for diagnosis, each separate additional evaluation episode, same site (List separately in addition to code for primary procedure)) is 60 percent of the recommended value for the base CPT code 88172 (Cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy for diagnosis, first evaluation episode, each site). We believe that the relative resources involved in furnishing an add-on service in this family would be reflected appropriately using the same 60 percent metric. To value CPT code 88341, we calculated 60 percent of the work RVU of the base CPT code 88342, which has a work RVU of 0.70; resulting in a work RVU of 0.42 for CPT code 88341.

(16) Morphometric Analysis In Situ Hybridization for Gene Rearrangement(s) (CPT Codes 88364, 88365, 88366, 88368, 88369, 88373, and 88374 and 88377)

For CY 2014, the in situ hybridization procedures, CPT codes 88365, 88367 and 88368, were revised to specify "each separately identifiable probe per block;" three new add-on codes (CPT codes 88364, 88373, 88369) were created to specify "each additional

² This chart only contains CY 2014 codes for which a HCPCS code is being used for CY 2015. Addendum B contains a complete list of CPT and HCPCS codes being recognized by Medicare under the PFS for CY 2015.

separately identifiable probe per slide;" and three new codes were created to specify "each multiplex probe stain procedure." We are establishing the RUC-recommended work RVUs as interim final for CY 2015 for CPT codes 88365, 88366, 88368, and 88377.

CPT code 88367 is the computer assisted version of morphometric analysis, analogous to 88368 which is the manual version. We have accepted the RUC recommended work RVU of 0.88 for 88368 which has 30 minutes of intraservice time. CPT code 88367 only has 25 minutes of intraservice time and we do not believe that the RUC recommended work RVU of 0.86 adequately reflects that change in time. We believe that the ratio of the intraservice times (25/30) applied to the work RVU (0.88) adequately reflects the difference in work. Therefore, we are assigning an interim final work RVU to CPT code 88367 of 0.73.

Similarly, CPT code 88374 is the computer assisted version of CPT code 88377 but with a drop in intraservice time from 45 minutes to 30 minutes. We believe applying this ratio to the work RVU of 88377 more accurately reflects the work. Therefore, we are assigning an interim final work RVU to CPT code 88374 of 0.93.

As discussed in the previous section, some of the add-on codes in this family had RUC-recommended work RVUs that were 60 percent of the work RVU of the base procedure and we applied that reduction to 88341. We believe this accurately reflects the resources used in furnishing these add-on codes. Accordingly, we used this methodology to establish interim final work RVUs of 0.53 for code 88364 (60 percent of the work RVU of CPT code 88365); 0.53 for CPT code 88369 (60 percent of the work RVU of CPT code 88368); and 0.43 for CPT code 88373 (60 percent of the work RVU of CPT code 88367).

(17) Electro-oculography (EOG VNG) CPT Codes 92270, 92540, 92541, 92542, 92544, 92543, and 92545)

After the RUC identified CPT code 92543 as potentially misvalued through the CMS-Other Source—Utilization over 250,000 screen, CPT revised the parentheticals for this code for CY 2015. We received RUC recommendations for CY 2015 for this code and other codes in the family. We are assigning the RUC-recommended work values for CPT codes 92270, 92540, 92541, 92542, 92544, and 92545. For CPT code 92543, however, we have been informed by the RUC that survey respondents may not have understood the revised code description for CPT code 92543, and thus the survey data may be unreliable.

As a result, we believe the most accurate information upon which to base work RVUs for CPT code 92543 is its existing work RVU. Therefore, we are establishing a work RVU of 0.10 for CPT code 92543 as interim final for CY 2015.

(18) Interventional Transesophageal Echocardiography (TEE) (CPT Codes 93312, 93313, 93314, 93315, 93316, 93317, 93318, 93355, and 93644)

For CY 2015, CPT code 93355 was created to describe transesophageal echocardiography during interventional cardiac procedures. The RUC provided recommendations for CPT code 93355, and for CPT codes 93312–93318 in order to ensure intra-family relativity. We are establishing the RUC-recommended work RVU of 2.40 as interim final for CY 2015 for CPT code 93318 and 4.66 for CPT code 93355.

The RUC based the work RVU for CPT code 93312 upon a crosswalk to CPT code 43247 (Esophagogastroduodenoscopy, flexible, transoral; with removal of foreign body). This code has significant differences from CPT code 93312. We have been unable to identify a CPT code with 30 minutes of intraservice time and 60 minutes of total time with a work RVU higher than 2.55. We believe this service is more similar to CPT code 75573 (Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3D image postprocessing, assessment of LV cardiac function, RV structure and function and evaluation of venous structures, if performed) since it has similar work, time and the same global period. Based upon this crosswalk, we are assigning CPT code 93312 a CY 2015 interim final work RVU of 2.55.

Due to CPT descriptor for CPT code 93315, we believe that the appropriate work for this service is reflected in the combined work of CPT codes 93316 and 93317, resulting in a CY 2015 interim final work RVU of 2.94.

For CPT codes 93313, 93314, 93316 and 93317, we are assigning CY 2015 interim final work RVUs based upon the 25th percentile values from the survey: 0.51 for CPT code 93313, 2.10 for CPT code 93314, 2.94 for CPT code 93315, 0.85 for CPT code 93316, 2.09 for CPT code 93317, and 4.66 for CPT code 93355. Each of these codes had a significant drop in intraservice time since the last valuation and RUC recommendations for higher work RVUs. As we have stated in the absence of information showing a change in intensity, we believe meaningful changes in time should be reflected in

the work RVUs. For these codes, we believe the 25th percentile survey values better describe the work and time involved in these procedures than the RUC recommendations and also help maintain appropriate relativity in the family. Additionally, we are refining the preservice and intraservice times for CPT codes 93314 and 93317 to 10 and 20 minutes, respectively, to maintain relativity among the interim final work RVUs and times.

(19) Subcutaneous Implantable Defibrillator Procedures (CPT Codes 33270, 33271, 33272, 33272, 93260, 93261 and 93644)

For CY 2015, the CPT Editorial Panel added the word "implantable" to the descriptors for several codes in this family and created several new codes, CPT codes 33270, 33271, 33272, 33272, 93260, 93261 and 93644. We received RUC recommendations for the new and revised codes. We are establishing the RUC-recommended work RVUs for all of the codes in this family except CPT code 93644. This code has an intraservice time of 20 minutes and a total time of 84 minutes. We disagree with the RUC-recommended crosswalk for CPT code 93644 which has an intraservice time of 29 minutes and a total time of 115 minutes and believe that a crosswalk to CPT code 32551 would be better as that code's intraservice time is 20 minutes and the total time is 83 minutes. Therefore, we are establishing a CY 2015 interim final work RVU of 3.29 for CPT code 93644.

(20) Duplex Scans (CPT Codes 93886, 93888, 93926, 93975, 93976, 93977, 93978, and 93979)

In the CY 2013 PFS final rule with comment period, we requested that the RUC assess the relativity among the entire family of duplex scans codes and recommend appropriate work RVUs. CMS also requested that the RUC consider CPT codes 93886, Transcranial Doppler study of the intracranial arteries; complete study, and 93888, Transcranial Doppler study of the intracranial arteries; limited study, in conjunction with the duplex scan codes in order to assess the relativity between and among those codes. The RUC reviewed this entire family of codes and provided recommendations for CY 2015. For CY 2015, we are establishing the RUC-recommended work RVUs as interim final for all of the codes in the family except CPT codes 93886, 93888, 93926, 93975, 93976, 93977, 93978, and 93979.

For several codes in this family with 10 minutes of intraservice time, the RUC recommended 0.50 work RVUs. We

believe that this relationship between intraservice time and work RVU accurately reflects the time and intensity involved, and should be used for the majority of the codes in the family. As a result, for CPT codes 93926, 93979, and 93888, which all have 10 minutes of intraservice time, we are assigning an interim final work RVU of 0.50.

For several codes in this family with 15 minutes of intraservice time, the RUC recommended work RVUs based upon the survey 25th percentile. We find this to appropriately reflect the work involved. Accordingly, for CPT codes 93975, 93976, and 93978, which all have 15 minutes of intraservice time, we are disagreeing with the RUC work RVU recommendations and assigning the 25th percentile of the survey as CY 2015 interim final values. Therefore, for CY 2015 we are establishing the following interim final work RVUs: 1.16 for CPT code 93975, 0.80 for CPT code 93976, 0.80 for CPT code 93978 and 0.50 for CPT code 93979. Lastly, we believe that the RUC recommendation for CPT code 93886 overvalues the work involved. We accepted the RUC recommendation for CPT code 93880 of 0.80 with an intraservice time of 15 minutes. CPT code 93886 has an intraservice time of 17 minutes. Applying the work RVU to time ratio of CPT code 93880 to the intraservice time of CPT code 93886 (results in our interim final value of 0.91 for CPT code 93886).

(21) Carotid Intima-Media Thickness Ultrasound (CPT Code 93895)

For CY 2015, a new code, CPT code 93895, describes the work of using carotid ultrasound to measure atherosclerosis and quantify the intima-media thickness. After review of this code, we determined that it is used only for screening and therefore, we are assigning a PFS procedure status indicator of N (Noncovered service) to CPT code 93895.

(22) Doppler Flow Testing (CPT Code 93990)

For CY 2015, the RUC provided a recommendation for CPT code 93990 which had been identified through the High Volume Growth Services where Medicare utilization increased by at least 100 percent from 2006 to 2011. The RUC recommended a work RVU of 0.60 for this service. Due to the similarity of this service to duplex scans, we are establishing RVUs for CPT code 93990 that are consistent with duplex scans with 10 minutes of intraservice time; which we discussed above in section E.4.18. We assigned it an interim final work RVU of 0.50.

(23) Electronic analysis of implanted neurostimulator (CPT Codes 95971 and 95972)

For CY 2015, the RUC reviewed CPT codes 95971 and 95972 because they were identified by the High Volume Growth Services screen which identifies services in which Medicare utilization increased by at least 100 percent from 2006 to 2011 screen. It is unclear to us why CPT code 95973, the add-on code to CPT code 95972, was not also surveyed. We are valuing CPT code 95971 based upon the RUC recommended work RVU of 0.78.

For CPT code 95972, we do not believe that the RUC recommended change in work RVU from 1.50 to 0.90 reflects the much more significant change in intraservice time from 60 minutes to 23 minutes. Therefore, we used a building block methodology to develop a work RVU of 0.80.

Even though the RUC did not survey 95973, we believe we should review it as part of this family. Not having a survey or RUC recommendations, we believe that the percent decrease in the work RVU from the base code 95972 should apply to this code. Therefore, we are establishing an interim final work RVU of 0.49 for CPT code 95973.

We note that the descriptor for CPT code 95972 was changed from “. . . first hour” to “. . . up to one hour.” We note that for Medicare purposes this code should only be billed when a majority of an hour is completed. We would also note that the add-on code should only be reported after a full 60 minutes of service is furnished.

The lack of a survey for CPT code 95973 along with the confusing descriptor language and intraservice time suggest the need for this family to be returned to CPT for clarification of the descriptor and then to the RUC for resurvey.

(24) Negative Pressure Wound Therapy (CPT Codes 97607, and 97608, and HCPCS codes G0456 and G0457)

Prior to CY 2013, the codes used to report negative pressure wound therapy were CPT codes 97605 and 97606, both of which were typically reported in conjunction with durable medical equipment that was paid separately. In the CY 2013 final rule with comment period, we created two HCPCS codes to provide a payment mechanism for negative pressure wound therapy services furnished to beneficiaries using equipment that is not paid for as durable medical equipment: G0456 (Negative pressure wound therapy, (for example, vacuum assisted drainage collection) using a mechanically-

powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters) and G0457 (Negative pressure wound therapy, (for example, vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 sq cm).

For CY 2015, two new codes, CPT codes 97607 and 97608, were created to describe negative pressure wound therapy with the use of a disposable system. In addition, CPT codes 97605 and 97606 were revised to specify the use of durable medical equipment. Based upon these the revised coding scheme for negative pressure wound therapy, we are deleting the G-codes. We are contractor pricing these codes for CY 2015. CPT codes 97607 and 97608 will be designated “Sometimes Therapy” on our Therapy Code List, which is consistent with the G-codes. The Therapy Code List is available at <http://www.cms.gov/Medicare/Billing/TherapyServices/index.html?redirect=/therapyservices>.”

(25) Application of Topical Fluoride Varnish (CPT Code 99188)

CPT Code 99188 is a new code for CY 2015 that describes the application of topical fluoride varnish to teeth. Since this code describes a service that involves the care of teeth, it is excluded from coverage under Medicare by section 1862(a)(12) of the Act, which provides “items and services in connection with the care, treatment, filling, removal, or replacement of teeth, or structures directly supporting the teeth are excluded from coverage.” Accordingly, we are assigning a PFS procedure status indicator of N (Noncovered service) to CPT code 99188.

(26) Advance Care Planning (CPT codes 99497 and 99498)

For CY 2015, the CPT Editorial Panel created two new codes describing advance care planning services: CPT code 99497 (Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health professional; first 30 minutes, face-to-face with the patient, family member(s)

and/or surrogate); and an add-CPT code 99498 (Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health professional; each additional 30 minutes (List separately in addition to code for primary procedure)). For CY 2015, we are assigning a PFS status indicator of "I" (Not valid for Medicare purposes. Medicare uses another code for the reporting and payment of these services.) to CPT codes 99497 and 99498 for CY 2015. However, we will consider whether to pay for CPT codes 99497 and 99498 after we have had the opportunity to go through notice and comment rulemaking.

c. Establishing Interim Final Direct PE RVUs for CY 2015

i. Background and Methodology

The RUC provides CMS with recommendations regarding direct PE inputs, including clinical labor, disposable supplies, and medical equipment, for new, revised, and potentially misvalued codes. We review the RUC-recommended direct PE inputs on a code-by-code basis, including the recommended facility PE inputs and/or nonfacility PE inputs. This review is informed by both our clinical assessment of the typical resource requirements for furnishing the service and our intention to maintain the principles of accuracy and relativity in the database. We determine whether we agree with the RUC's recommended direct PE inputs for a service or, if we disagree, we refine the PE inputs to represent inputs that better reflect our estimate of the PE resources required to furnish the service in the facility and/or nonfacility settings. We also confirm that CPT codes should have facility and/or nonfacility direct PE inputs and make changes based on our clinical judgment and any PFS payment policies that would apply to the code.

We have accepted for CY 2015, as interim final and without refinement, the direct PE inputs based on the recommendations submitted by the RUC for the codes listed in Table 28. For the remainder of the RUC's direct PE recommendations, we have accepted the PE recommendations submitted by the RUC as interim final, but with refinements. These codes and the refinements to their direct PE inputs are listed in Table 31.

We note that the final CY 2015 PFS direct PE input database reflects the refined direct PE inputs that we are adopting on an interim final basis for

CY 2015. That database is available under downloads for the CY 2015 PFS final rule with comment period on the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>. We also note that the PE RVUs displayed in Addenda B and C reflect the interim final values and policies described in this section. All PE RVUs adopted on an interim final basis for CY 2015 are included in Addendum C and are open for comment in this final rule with comment period.

TABLE 28—CY 2015 INTERIM FINAL CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITHOUT REFINEMENT

HCPCS	Short Descriptor
11980	Implant hormone pellet(s)
22512	Vertebroplasty addl inject
22515	Perq vertebral augmentation
22856	Cerv artific disectomy
27280	Fusion of sacroiliac joint
31620	Endobronchial us add-on
33270	Ins/rep subq defibrillator
33271	Insj subq impltbl dfb elctrd
33272	Rmvl of subq defibrillator
33273	Repos prev impltbl subq dfb
33951	Ecmo/eccls insj prph cannula
33952	Ecmo/eccls insj prph cannula
33953	Ecmo/eccls insj prph cannula
33954	Ecmo/eccls insj prph cannula
33955	Ecmo/eccls insj ctr cannula
33956	Ecmo/eccls insj ctr cannula
33957	Ecmo/eccls repos perph cnula
33958	Ecmo/eccls repos perph cnula
33959	Ecmo/eccls repos perph cnula
33962	Ecmo/eccls repos perph cnula
33963	Ecmo/eccls repos perph cnula
33964	Ecmo/eccls repos perph cnula
33969	Ecmo/eccls rmvl perph cannula
33984	Ecmo/eccls rmvl prph cannula
33985	Ecmo/eccls rmvl ctr cannula
33986	Ecmo/eccls rmvl ctr cannula
33988	Insertion of left heart vent
33989	Removal of left heart vent
36818	Av fuse uppr arm cephalic
36819	Av fuse uppr arm basilic
36820	Av fusion/forearm vein
36821	Av fusion direct any site
36825	Artery-vein autograft
36830	Artery-vein nonautograft
36831	Open thrombect av fistula
36832	Av fistula revision open
36833	Av fistula revision
37218	Stent placemt ante carotid
43180	Esophagoscopy rigid trnso
52441	Cystourethro w/implant
55840	Extensive prostate surgery
55842	Extensive prostate surgery
55845	Extensive prostate surgery
58541	Lsh uterus 250 g or less
58542	Lsh w/t/o ut 250 g or less
58543	Lsh uterus above 250 g
58544	Lsh w/t/o uterus above 250 g
58570	Tlh uterus 250 g or less
58571	Tlh w/t/o 250 g or less
58572	Tlh uterus over 250 g
58573	Tlh w/t/o uterus over 250 g

TABLE 28—CY 2015 INTERIM FINAL CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITHOUT REFINEMENT—Continued

HCPCS	Short Descriptor
64486	Tap block unil by injection
64487	Tap block uni by infusion
64488	Tap block bi injection
64489	Tap block bi by infusion
66179	Aqueous shunt eye w/o graft
66180	Aqueous shunt eye w/graft
66184	Revision of aqueous shunt
66185	Revise aqueous shunt eye
67036	Removal of inner eye fluid
67039	Laser treatment of retina
67040	Laser treatment of retina
67041	Vit for macular pucker
67042	Vit for macular hole
67043	Vit for membrane dissect
67255	Reinforce/graft eye wall
70496	Ct angiography head
70498	Ct angiography neck
76770	Us exam abdo back wall comp
76775	Us exam abdo back wall lim
76856	Us exam pelvic complete
76857	Us exam pelvic limited
77080	Dxa bone density axial
77316	Brachytx isodose plan simple
77317	Brachytx isodose intermed
77318	Brachytx isodose complex
88348	Electron microscopy
88356	Analysis nerve
91200	Liver elastography
92145	Corneal hysteresis deter
92541	Spontaneous nystagmus test
92542	Positional nystagmus test
92544	Optokinetic nystagmus test
92545	Oscillating tracking test
93260	Prgmrng dev eval impltbl sys
93261	Interrogate subq defib
93644	Electrophysiology evaluation
97610	Low frequency non-thermal us

ii. Common Refinements

Table 31 details our refinements of the RUC's direct PE recommendations at the code-specific level. In this section, we discuss the general nature of some common refinements and the reasons for particular refinements.

(a) Changes in Physician Time

Some direct PE inputs are directly affected by revisions in work time described in section II.E.3.a. of this final rule with comment period. We note that for many codes, changes in the intraservice portions of the work time and changes in the number or level of postoperative visits included in the global periods result in corresponding changes to direct PE inputs. We also note that, for a significant number of services, especially diagnostic tests, the procedure time assumptions used in determining direct PE inputs are distinct from, and therefore not dependent on, work intraservice time assumptions. For these services, we do not make refinements to the direct PE

inputs based on changes to estimated work intraservice times.

Changes in Intraservice Work Time in the Nonfacility Setting. For most codes valued in the nonfacility setting, a portion of the clinical labor time allocated to the intraservice period reflects minutes assigned for assisting the practitioner with the procedure. To the extent that we are refining the times associated with the intraservice portion of such procedures, we have adjusted the corresponding intraservice clinical labor minutes in the nonfacility setting.

For equipment associated with the intraservice period in the nonfacility setting, we generally allocate time based on the typical number of minutes a piece of equipment is being used, and therefore, not available for use with another patient during that period. In general, we allocate these minutes based on the description of typical clinical labor activities. To the extent that we are making changes in the clinical labor times associated with the intraservice portion of procedures, we have adjusted the corresponding equipment minutes associated with the codes.

Changes in the Number or Level of Postoperative Office Visits in the Global Period. For codes valued with postservice office visits during a global period, most of the clinical labor time allocated to the postservice period reflects a standard number of minutes allocated for each of those visits. To the extent that we are refining the number or level of postoperative visits, we have modified the clinical staff time in the postservice period to reflect the change. We note that until the global periods are transitioned, consistent with other policies finalized in this rule, we will make these refinements. For codes valued with postservice office visits during a global period, we allocate standard equipment for each of those visits. To the extent that we are making a change in the number or level of postoperative visits associated with a code, we have adjusted the corresponding equipment minutes. For codes valued with postservice office visits during a global period, a certain number of supply items are allocated for each of those office visits. To the extent that we are making a change in the number of postoperative visits, we have adjusted the corresponding supply item quantities associated with the codes. We note that many supply items associated with postservice office visits are allocated for each office visit (for example, a minimum multi-specialty visit pack (SA048) in the CY 2015 direct PE input database). For these supply items, the quantities in the direct PE input database should reflect the

number of office visits associated with the code's global period. However, some supply items are associated with postservice office visits but are only allocated once during the global period because they are typically used during only one of the postservice office visits (for example, pack, post-op incision care (suture) (SA054) in the direct PE input database). For these supply items, the quantities in the direct PE input database reflect that single quantity.

These refinements are reflected in the final CY 2015 PFS direct PE input database and detailed in Table 31.

(b) Equipment Minutes

In general, the equipment time inputs reflect the sum of the times within the intraservice period when a clinician is using the piece of equipment, plus any additional time the piece of equipment is not available for use for another patient due to its use during the designated procedure. In cases where equipment times included time for clinical labor activities in the pre-service period, we have refined these times to remove the minutes associated with these tasks, since the pre-service period ends "when patient enters office/facility for surgery/procedure." Although some services include equipment that is typically unavailable during the entire clinical labor service period, certain highly technical pieces of equipment and equipment rooms are less likely to be used by a clinician for all tasks associated with a service, and therefore, are typically available for other patients during the preservice and postservice components of the service period. We adjust those equipment times accordingly. We refer interested stakeholders to our extensive discussion of these policies in the CY 2012 PFS final rule with comment period (76 FR 73182–73183) and in section II.G.2.b. of this final rule with comment period. We are refining the CY 2015 RUC direct PE recommendations to conform to these equipment time policies. These refinements are reflected in the final CY 2015 PFS direct PE input database and detailed in Table 31.

(c) Moderate Sedation Inputs

In the CY 2012 PFS final rule (76 FR 73043–73049), we finalized a standard package of direct PE inputs for services where moderate sedation is considered inherent in the procedure. In section II.A. of this final rule with comment period, we finalized a refinement to the standard package to include a stretcher for the same length of time as the other equipment items in the standard package. We are refining the CY 2015 RUC direct PE recommendations to

conform to these policies. This includes the removal of a power table where it was included during the intraservice period, as the stretcher takes the place of the table. These refinements are reflected in the final CY 2015 PFS direct PE input database and detailed in Table 31.

(d) Standard Minutes for Clinical Labor Tasks

In general, the preservice, intraservice period, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the recommended direct PE inputs on "PE worksheets." For most of these described tasks, there are a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. At times, the RUC recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, CMS reviews the deviations from the standards to assess whether they are clinically appropriate. Where the RUC-recommended exceptions are not accepted, we refine the interim final direct PE inputs to match the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M or other evaluation service, we remove the preservice clinical labor tasks so that the inputs are not duplicative and reflect the resource costs of furnishing the typical service.

In some cases the RUC recommendations include additional minutes described by a category called "other clinical activity," or through the addition of clinical labor tasks that are different from those previously included as standard. In these instances, CMS reviews the tasks as described in the recommendation to determine whether they are already incorporated into the total number of minutes based on the standard tasks. Additionally, CMS reviews these tasks in the context of the kinds of tasks delineated for other services under the PFS. For those tasks that are duplicative or not separately incorporated for other services, we do not accept those additional clinical labor tasks as direct inputs. For example, as we have previously discussed (78 FR 74308), we believe that quality assurance documentation tasks for services across the PFS are already accounted for in the overall estimate of clinical labor time. We do not believe that it would serve the relativity of the direct PE input database were additional minutes added for each clinical task that

could be discretely described for every code. These refinements are reflected in the final CY 2015 PFS direct PE input database and detailed in Table 31.

(e) New Supply and Equipment Items

The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised, and potentially misvalued codes. Some recommendations include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended a new item be created and has facilitated CMS's pricing of that item by working with the specialty societies to provide sales invoices to us.

We received invoices for several new supply and equipment items for CY 2015. We have accepted the majority of these items and added them to the direct PE input database. Tables 29 and 30 detail the invoices received for new and existing items in the direct PE

database. As discussed in section II.A. of this final rule with comment period, we encourage stakeholders to review the prices associated with these new and existing items to determine whether these prices appear reasonable. Where prices appear unreasonable, we encourage stakeholders to provide invoices that provide more accurate pricing for these items in the direct PE database. We remind stakeholders that due to the budget neutral nature of the PFS, increased prices for any items in the direct PE database decrease the pool of PE RVUs available to all other PFS services. Tables 29 and 30 also include the number of invoices received as well as the number of nonfacility allowed services for procedures that use these equipment items. In cases where large numbers of allowed services exist, we question pricing the item based upon a single invoice. We are concerned that the single invoice may not be reflective of typical costs for these items and

encourage stakeholders to provide additional invoices.

In some cases we cannot adequately price a newly recommended item due to inadequate information. In some cases, no supporting information regarding the price of the item has been included in the recommendation to create a new item. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, price quotes instead of paid invoices). In cases where the information provided allowed us to identify clinically appropriate proxy items, we have used existing items as proxies for the newly recommended items. In other cases, we have included the item in the direct PE input database without an associated price. Although including the item without an associated price means that the item does not contribute to the calculation of the PE RVU for particular services, it facilitates our ability to incorporate a price once we are able to do so.

TABLE 29—INVOICES RECEIVED FOR NEW DIRECT PE INPUTS

CPT/HCPCS codes	Item name	CMS code	Average price	No. of invoices	Non-facility allowed services for HCPCS codes using this item (or projected services for new CPT codes*)
20604, 20606, 20611 ..	ultrasound transmission gel, sterile	SJ089	\$1.71	1	748248*
22512	(single use)				
22512	10g IVAS drill	SD292	139.33	1	99*
29200, 29240, 29260, 29280, 29520, 29530, 29540, 29550.	10g cannulae	SD293	86.11	1	99*
29200, 29240, 29260, 29280, 29520, 29530, 29540, 29550.	foam underwrap	SG097	0.0043 per inch	1	415513
29200, 29240, 29260, 29280, 29520, 29530, 29540, 29550.	rigid strapping tape (15 yards)	SG098	0.018 per inch ..	1	415513
29200, 29240, 29260, 29280, 29520, 29530, 29540, 29550.	skin prep barrier wipes	SM029	0.20	1	415513
31620	Flexible dual-channeled EBUS broncho-scope, with radial probe.	EQ361	160,260.06	6	107
31620	Video system, Ultrasound (processor, digital capture, monitor, printer, cart).	ER099	13,379.57	6	107
31620	EBUS, single use aspiration needle, 21 g	SC102	145.82	5	107
31620	Balloon for Bronchoscopy Fiberscope	SD294	28.68	4	107
52441, 52442	Urolift Implant and implantation device	SD291	775.00	10	12*
64486, 64488	ultrasound needle	SC101	12.81	4	46851*
64487, 64489	continuous peripheal nerve block tray	SA116	23.69	1	802*
77063	multimodality software	ED051	11,570.00	12	297529*
88341	Anti CD45 Monoclonal Antibody	SL495	3.61 per test	1	917673*
88344	34 Beta E12	SL496	4.27 per test	1	51591*
88348	Digital Printer	ED048	774.89	1	641
88348	Carbon Coater	EQ366	22,540.08	1	641
88348	Diamond Milling Tool	EQ365	1,714.00	1	641
88356, 88348	Electron Microscopy Tissue processor	EP115	13,119.00	2	19134
88356, 88348	Block face milling machine	EQ363	18,139.00	1	19134
88356, 88348	Glass Knife Breaker	EQ364	9,585.14	1	19134
88364	CMV DNA Probe Cocktail	SL500	0.10 per ul	1	3376*
88341, 88342, 88344, 88364, 88365, 88367, 88368, 88369, 88373.	Universal Detection Kit	SA117	4.00	1	1380597
88365	EBER positive control slide	SL507	20.15	1	8440
88365	(EBER) DNA Probe Cocktail	SL497	8.57 per test	2	8440

TABLE 29—INVOICES RECEIVED FOR NEW DIRECT PE INPUTS—Continued

CPT/HCPCS codes	Item name	CMS code	Average price	No. of invoices	Non-facility allowed services for HCPCS codes using this item (or projected services for new CPT codes*)
88365, 88366, 88367, 88368, 88374, 88377.	VP-2000 Processor	EP116	30,800.00	1	228243
88367, 88368	Kappa Probe Cocktails	SL498	0.10 per ul	1	36634
88369, 88373	Lambda Probe Cocktail	SL499	0.10 per ul	1	24423*
88380, 88381	Surface Decontaminant (DNA Away)	SL494	0.07 per ml	1	6649
91200	Fibroscan	ER101	124,950.00	1	87*
92145	Ocular Response Analyzer	EQ360	12,000.00	3	Unknown
92541, 92542, 92544, 92545.	VNG Recording System	EQ367	29,607.50	2	101139
93702	BIS monitoring system (bioimpedance spectroscopy).	EQ359	3,316.93	1	Unknown
93702	electrode, BIS (bioimpedance spectroscopy)	SD290	28.33	1	Unknown
96127	Beck Youth Inventory, Second Edition (BYI-II); Combination Inventory Booklet.	SK119	1.96 per booklet	1	Unknown
97610	MIST Therapy System	EQ372	28,000.00	2	2*
97610	MIST Therapy Cart	EQ368	1,250.00	1	2*
97610	kit, low frequency ultrasound wound therapy (MIST).	SA119	63.33	3	2*
99188	CavityShield 5% Varnish .25mL	SH106	0.91	1	Unknown
G0277	HBOT air break breathing apparatus demand system (hoses, masks, penetrator and demand valve).	EQ362	986.00	1	153044*

TABLE 30—INVOICES RECEIVED FOR EXISTING DIRECT PE INPUTS

CPT/HCPCS codes	Item name	CMS code	Current price	Updated price	% Change	No. of invoices	Non-facility allowed services for HCPCS codes using this item
20983, 47383.	cryosurgery system (for tumor ablation).	EQ302	missing	\$37,500.00	2	22 *
20983, 47383.	gas, argon	SD227	\$0.25 per cubic foot ..	0.32 per cubic foot	28	1	22 *
20983, 47383.	gas, helium	SD079	0.25 per cubic foot	0.57 per cubic foot	128	1	22 *
31627	system, navigational bronchoscopy (superDimension).	EQ326	137,800.00	189,327.66	37	4	37
31627	kit, locatable guide, ext. working channel, w-b-scope adapter.	SA097	995.00	1,063.67	7	3	37
64561	kit, percutaneous neuro test stimulation.	SA022	305.00	420.00	38	1	8229
88348	camera, digital system, for electron microscopy.	ED006	41,000.00	82,000.00	100	1	641
88348, 88356.	microtome, ultra	ER043	25,950.00	34,379.00	32	1	19134
G0277	HBOT (hyperbaric oxygen therapy) monochamber, incl. gurney and integrated grounding assembly.	EQ131	125,000.00	127,017.98	2	1	153044 *

* New procedure—Projected volume.

(f) Recommended Items That Are Not Direct PE Inputs

In some cases, the recommended direct PE inputs included items that are not clinical labor, disposable supplies, or medical equipment resources. We have addressed these kinds of recommendations in previous rulemaking and in sections II.G.2.b. and II.B.4.a. of this final rule with comment period. Refinements to adjust for these recommended inputs are reflected in the final CY 2015 PFS direct PE input database and detailed in Table 31.

(g) Film-to-Digital Migration

As discussed in section II.A.3 of this final rule with comment period, we are finalizing our policy to remove equipment and supply inputs associated with film technology from the direct PE database. Since the recommendations we received for 2015 were prepared before the transition occurred, in some cases, the RUC recommendations included film inputs. Where recommendations included these inputs, we have removed these inputs and replaced them with “PACS workstation proxy” as described in section II.A.3 of this final rule with comment period. Since the film-to-digital transition results from our acceptance of a RUC recommendation, we do not consider the removal of these items to be refinements of RUC recommendations, and therefore do not include them in Table 31.

(h) Pre-Service and Post-Service Tasks for Add-On Codes

In general, we believe that certain pre-service and post-service tasks are not repeated for services reported using add-on codes. In some cases, we also believe that the time for certain equipment items are not duplicated for add-on codes. In these cases, we removed the time associated with those tasks and/or equipment items from those codes. These refinements appear in Table 31.

iii. Code-Specific Refinements**(a) Rib Fractures (CPT Codes 21811, 21812, and 21813)**

For the newly created rib fracture codes, which are frequently furnished as emergency surgeries, the RUC did not include time for the standard pre-service activities “Provide pre-service education/obtain consent” and “Follow-up phone calls & prescriptions.” However, the RUC recommendation included time for pre-service activities “Complete pre-service diagnostic & referral forms,” “Coordinate pre-surgery services,” and “Schedule space and

equipment in facility.” Since these codes would typically be provided as emergency surgeries, we question whether these tasks would typically be performed.

We reviewed other emergency procedures in the PFS to determine whether pre-service clinical labor activities were typically included in the PE worksheets. We found that the recommendations for these procedures were inconsistent. Therefore, we will not remove the time allocated for these clinical labor activities at this time. However, we believe that for emergency procedures, none of the pre-service tasks listed above would typically be performed. We seek comment to clarify this issue, and plan to consider this issue in future rulemaking.

As discussed earlier in this section of this final rule with comment period, we have valued CPT codes 21811, 21812, and 21813 as 0-day globals. We have therefore removed direct PE inputs associated with the postoperative visits.

(b) Percutaneous Vertebroplasty and Augmentation (CPT Codes 22510, 22511, 22512, 22513, 22514, and 22515)

The RUC recommendation regarding add-on CPT code 22512 (Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance, each additional cervicothoracic or lumbosacral vertebral body)) included new supply item “10g IVAS drill.” We note that the recommendations for the base codes did not contain this supply item, and the vertebroplasty kit does not appear to contain this drill either. We do not understand why the drill would be required for the add-on code when it is not required for the base code. Therefore, we will not include supply item “10g IVAS drill” in CPT code 22512 at this time.

(c) Endobronchial Ultrasound (EBUS) (CPT Code 31620)

As indicated earlier in this section of this final rule with comment period, we are maintaining the CY 2014 work RVU for CPT code 31620 in light of our concerns regarding coding structure. As such, we are maintaining the CY 2014 direct PE inputs for 31620 as well.

(d) Breast Tomosynthesis (CPT Codes 77061, 77062, and 77063)

For CY 2015, the CPT Editorial Panel created three codes to describe digital breast tomosynthesis services: 77061 (Digital breast tomosynthesis; unilateral), 77062 (Digital breast tomosynthesis; bilateral) and 77063 (Screening digital breast tomosynthesis,

bilateral (List separately in addition to code for primary procedure)). For these newly created codes, the RUC recommended creating a new equipment item, “room, breast tomosynthesis”, at a price of \$667,669, as well as a list of items contained in the room. We believe that several of the items included in the room are not appropriately characterized as direct costs. We also believe that the creation of rooms sometimes causes confusion when items in the room are also included as stand-alone PE inputs, as specialty societies do not consider the items included in the room when preparing the PE worksheets. Further, we believe that the prices for the rooms sometimes result in less transparency, as prices for items within the room tend to remain static over time. Therefore, we are not creating this new equipment item, but will instead include the individual equipment items that we believe are appropriately characterized as direct costs.

The price for the digital breast tomosynthesis unit indicated on the invoice received by the RUC was \$498,412. We received many invoices for this equipment item with an average price of \$381,380. Therefore, we will create a new equipment item “DBT unit”, at a price of \$381,380.

The RUC also recommended including a new equipment item, “PACS cache”, for these procedures. We do not believe that digital storage constitutes a direct cost, as it is not individually allocable to an individual patient for a particular service. . Therefore, we will not add this new equipment item to the direct PE database.

(e) Radiation Treatment (CPT Codes 77385, 77386, 77387, 77402, 77407, 77412)

For CY 2015, the CPT Editorial Panel revised the set of codes that describe radiation treatment delivery services. These revisions included the addition and deletion of several codes and the development of new guidelines and coding instructions. Due to the significant code restructuring and potential for changes in payment, some specialty societies representing providers of radiation treatment services have requested that we delay implementation of the new code set. We believe that given the large scale of the changes in this code set restructuring, in the context of our upcoming revised process for valuing new, revised, and potentially misvalued codes, it is prudent to propose the values for the revised code set in the CY 2016 rule

with opportunity for public comment prior to establishing payment rates.

(f) Immunohistochemistry (CPT Codes 88341, 88342, and 88344)

The RUC recommended including supply item “UltraView Universal DAB Detection Kit” (SL488) for CPT codes 88341, 88342, and 88344, which is priced at \$10.49 per kit, and “UltraView Universal Alkaline Phosphatase Red Detection Kit”, which is priced at \$20.64. We noted that for other similar services, CPT codes 88364, 88365, 88367, 88368, 88369, and 88373, the RUC recommended including supply item “Universal Detection Kit” (SA117), which is priced at \$4.00 per kit. After reviewing information about these two kits, we believe that functions provided by SL488 and SL489 are also provided by SA117. The recommendations did not explain why the more expensive kit was necessary for 88341, 88342, and 88344 when the less expensive kit was sufficient for CPT codes 88364, 88365, 88367, 88368, 88369, and 88373. Absent any rationale for the use of the more expensive kit, we are including SA117 for 88341, 88342, and 88344 in place of SL488.

(g) Electron Microscopy (CPT Code 88348)

The RUC recommended including a new supply item, “diamond milling tool”, for use with CPT code 88348. However, upon reviewing the invoice, we believe that “diamond milling tool” is more appropriately characterized as equipment. We have therefore created an equipment item for this tool, as listed in Table 29.

(h) Morphometric Analysis (CPT Codes 88364, 88365, 88366, 88367, 88373, 88374, 88377, 88368, and 88369)

The CPT Editorial Panel revised the in situ hybridization codes (88365, 88367, and 88368) and created three new add-on codes for reporting each additional separately identifiable probe per slide. The RUC reviewed CPT codes 88365, 88367, and 88368, among other services in this family, in October 2013 and recommended direct inputs for these procedures, including supply item “kit, FISH paraffin pretreatment” (SL195), with quantities of 1 unit for CPT code 88365, 0.75 units for CPT code 88367, and 1 unit for CPT code 88368.

After the CY 2014 PFS final rule with comment period was published, the specialty societies determined that additional clarification was necessary, and requested that the CPT Editorial Panel review the entire family again. The CPT editorial panel added three new codes for “each multiplex probe

stain procedure.” The specialty societies then resurveyed these procedures. The RUC reviewed the entire family at the April 2014 meeting and recommended supply item SL195 with a quantity of 2 units for CPT code 88365, 1.4 units for CPT code 88367, and 2 units for CPT code 88368. These quantities are double what the RUC recommended to us in October 2013, which was 1 unit for CPT code 88365, 0.75 units for CPT code 88367, and one unit for CPT code 88368. Without an explanation for this significant change, we are including SL195 with the following quantities: 1 unit for CPT code 88365, 0.75 units for CPT code 88367, and 1 unit for CPT code 88368. Similarly, for add-on services CPT codes 88364, 88366, 88369, 88373, 88374, and 88377, more than one unit of SL195 was included. We believe that the unit of the kit should be consistent between the base code and the add-on code. We will therefore include 1 unit of SL195 for CPT codes 88364, 88366, 88369, and 88377, and 0.75 units for CPT codes 88373 and 88374. We are also interested in learning more about why a partial kit would be used in furnishing the typical service.

CPT codes 88374 and 88377, which are add-on codes, contain more than one unit of supply item “kit, HER-2/neu DNA Probe” (SL196). Because these codes describe a service that includes a single specimen with one stain, we do not understand why more than one kit would be required. We have therefore included a unit of 1 for SL196 in CPT codes 88374 and 88377.

We also believe that the units of positive control slides and negative control slides should be consistent throughout this entire family. We note that CPT codes 88367, 88373, and 88374 included a recommended 0.2 units of positive and/or negative control slide; supply items SL118 and SL119 for CPT code 88367, supply items SL120 and SL121 for CPT code 88373, and supply items SL184 and SL185 for CPT code 88374. However, for CPT codes 88368, 88369, and 88377, the recommendation included 0.5 units of the positive and/or negative control slide (supply item SL112 for CPT codes 88368 and 88369, and supply items SL184 and SL185 for CPT code 88377). No rationale was provided for why a greater quantity of the control slide would be required. Therefore, we will include 0.2 units of positive and/or negative control slides, as appropriate, to maintain consistency throughout this family of codes.

As with the positive and negative control slides, we believe that the number of units of supply item SL498 (“Kappa probe cocktails”) and SL499

(Lambda probe cocktails”) should be consistent across procedures. The recommendations for CPT codes 88367 and 88373 contain 28 ul of SL498 for 88367 and 27 ul of SL499 for 88373. Therefore, to maintain consistency, we refined the units of SL498 for CPT code 88368 and SL499 for CPT code 88369 to 28 ul.

The RUC recommended a quantity of 1.6 for SL497 (“(EBER) DNA Probe Cocktail” for CPT code 88365. Since this procedure describes a single stain, and the stain needs to be added to the positive control slide and the specimen slide, we believe that a quantity of 2 is more appropriate. We have therefore included 2 units of SL497 for CPT code 88365.

The RUC recommendation also included a new equipment item “VP-2000 processor” (EP116). Among the purposes of this equipment item is to reduce the amount of technician time needed to complete the clinical labor task. However, in the recommendations we received, rather than the clinical labor time for these codes decreasing with the addition of this new equipment item, the RUC recommended increased clinical labor times associated with this task for CPT codes 88365, 88366, 88368, and 88377 increased. We are unable to reconcile as typical the new equipment item, which is intended to reduce technician time, with the increased technician time for this same clinical labor task. Therefore, we will not allocate time for equipment item “VP-2000 processor” (EP116) in CPT codes 88365, 88366, 88368, and 88377.

(h) Microdissection (CPT Codes 88380 and 88381)

In reviewing the RUC recommendations for CPT code 88380, the work vignette indicated that the microdissection is performed by the pathologist. However, the PE worksheet also included several subtasks of “Microdissect each stained slide sequentially while reviewing H and E stained slide” that are performed by the cytotechnologist. Since we do not believe that both the pathologist and the cytotechnologist are completing these tasks, we have refined out the lines associated with the specific tasks we believe are completed by the pathologist. Table 31 details our refinements to the clinical labor tasks.

(j) Interventional Transesophageal Echocardiography (TEE) (CPT Codes 93312 and 93314)

CPT code 93314 describes a service in which the acquisition and interpretation of images is furnished by a different practitioner than the placement of the

probe. CPT code 93312 includes all services encompassed by CPT code 93314 and included a recommendation for 30 minutes of assist physician time. We do not believe that CPT code 93314 should have more clinical labor than CPT code 93312, which is the more extensive code. We have therefore refined this time to 30 minutes, which is the same as the time allocated to 93312. We also note that the time allocated to equipment item “room, ultrasound, vascular” (EL016) was affected by this refinement.

(k) Hyperbaric Oxygen Therapy (HBOT) (HCPCS Code G0277)

We received a RUC recommendation for CPT code 99183 (Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session), which included significant increases to the direct PE inputs, which assumes a treatment time of 120 minutes. Currently, CPT code 99183 is used for both the professional attendance and supervision and the actual treatment

delivery. Stakeholders have pointed out that although we include the PE inputs for treatment delivery in this code, the descriptor describes only attendance and supervision. We note that under the OPPS, the treatment is reported using separate treatment code C1300 (Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval). After considering this issue, we believe the OPPS approach would also be appropriate for the PFS. We are therefore creating a G-code to report the treatment delivery and to maintain consistency with the OPPS coding. We will use the same descriptor as previously used for OPPS code C1300 for a timed 30-minute code, which can then be used across settings. To value this G-code, we used the RUC recommended direct PE inputs for 99183 and adjusted them to align with the 30 minute treatment interval.

In reviewing the recommended direct PE inputs, we observed that the quantity of oxygen increased significantly relative to the previous value. To better understand this change, we reviewed

the instruction manual for the most commonly used HBOT chamber, which provide guidance regarding the quantity of Oxygen used. Based on our review, we determined that 12,000, rather than 47,000, was the typical number of units. Therefore, in aligning the direct PE inputs as described above, we first adjusted the units of oxygen to 12,000 for the recommended 120 minute time, and subsequently adjusted it to align with the 30 minute G-code.

(l) EOG VNG (CPT code 92543)

As described earlier in this section of this final rule with comment period, we are maintaining the CY 2014 work RVU for CPT code 92543 due to possible confusion among survey respondents. Similarly, we are also maintaining the CY 2014 direct PE inputs for 92543.

These refinements, as well as other applicable standard and common refinements for these codes, are reflected in the final CY 2015 PFS direct PE input database and detailed in Table 31.

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**TABLE 31: CY 2015 INTERIM FINAL CODES WITH DIRECT PE INPUT RECOMMENDATIONS
ACCEPTED WITH REFINEMENTS**

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommendation or current value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change
20604	Drain/inj joint/bursa w/us	L037D	RN/LPN/MTA	F	Conduct phone calls/call in prescriptions	3	0	Typically billed with an E/M service	\$-1.11
		L037D	RN/LPN/MTA	NF	Conduct phone calls/call in prescriptions	3	0	Typically billed with an E/M service	\$-1.11
20606	Drain/inj joint/bursa w/us	L037D	RN/LPN/MTA	F	Conduct phone calls/call in prescriptions	3	0	Typically billed with an E/M service	\$-1.11
		L037D	RN/LPN/MTA	NF	Conduct phone calls/call in prescriptions	3	0	Typically billed with an E/M service	\$-1.11
20611	Drain/inj joint/bursa w/us	L037D	RN/LPN/MTA	F	Conduct phone calls/call in prescriptions	3	0	Typically billed with an E/M service	\$-1.11
		L037D	RN/LPN/MTA	NF	Conduct phone calls/call in prescriptions	3	0	Typically billed with an E/M service	\$-1.11
20983	Ablate bone tumor(s) perq	EF018	stretcher	NF		60	193	Standard equipment and time for moderate sedation	\$0.68
		EF027	table, instrument, mobile	NF		134	193	Standard equipment and time for moderate sedation	\$0.08
		EL007	room, CT	NF		134	133	Refined equipment time to conform to established policies for highly technical equipment.	\$-4.87
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		194	193	Standard equipment and time for moderate sedation	\$-0.01
		EQ032	IV infusion pump	NF		194	193	Standard equipment and time for moderate sedation	\$-0.01
		EQ168	light, exam	NF		194	133	Refined equipment time to conform to established	\$-0.26

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommendation or current value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change
								policies for non-highly technical equipment.	
		EQ302	cryosurgery system (for tumor ablation)	NF		134	133	Refined equipment time to conform to established policies for highly technical equipment.	\$-0.10
21811	Optx of rib fx w/fixj scope	L037D	RN/LPN/MTA	F	Discharge day management 99238 --12 minutes	12	0	Post-operative visits removed; see preamble text.	\$-4.44
		EF014	light, surgical	PO		72	0	Post-operative visits removed; see preamble text.	\$-0.72
		EF031	table, power	PO		72	0	Post-operative visits removed; see preamble text.	\$-1.18
		SA048	pack, minimum multi-specialty visit	PO		2	0	Post-operative visits removed; see preamble text.	\$-2.29
		SA052	pack, post-op incision care (staple)	PO		1	0	Post-operative visits removed; see preamble text.	\$-5.06
21812	Treatment of rib fracture	L037D	RN/LPN/MTA	F	Discharge day management 99238 --12 minutes	12	0	Post-operative visits removed; see preamble text.	\$-4.44
		EF014	light, surgical	PO		99	0	Post-operative visits removed; see preamble text.	\$-0.99
		EF031	table, power	PO		99	0	Post-operative visits removed; see preamble text.	\$-1.62
		SA048	pack, minimum multi-specialty visit	PO		3	0	Post-operative visits removed; see preamble text.	\$-3.43
		SA052	pack, post-op incision care (staple)	PO		1	0	Post-operative visits removed; see preamble text.	\$-5.06
21813	Treatment of rib fracture	L037D	RN/LPN/MTA	F	Discharge day management 99238 --12 minutes	12	0	Post-operative visits removed; see preamble text.	\$-4.44

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommendation or current value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change
		EF014	light, surgical	PO		99	0	Post-operative visits removed; see preamble text.	\$-0.99
		EF031	table, power	PO		99	0	Post-operative visits removed; see preamble text.	\$-1.62
		SA048	pack, minimum multi-specialty visit	PO		3	0	Post-operative visits removed; see preamble text.	\$-3.43
		SA052	pack, post-op incision care (staple)	PO		1	0	Post-operative visits removed; see preamble text.	\$-5.06
22513	Perq vertebral augmentation	SA053	pack, post-op incision care (suture & staple)	NF		1	0	No justification provided for use of staple and suture pack. Suture pack sufficient in the typical procedure.	\$-6.11
		SA054	pack, post-op incision care (suture)	NF		0	1	No justification provided for use of staple and suture pack. Suture pack sufficient in the typical procedure.	\$4.91
22514	Perq vertebral augmentation	SA053	pack, post-op incision care (suture & staple)	NF		1	0	No justification provided for use of staple and suture pack. Suture pack sufficient in the typical procedure.	\$-6.11
		SA054	pack, post-op incision care (suture)	NF		0	1	No justification provided for use of staple and suture pack. Suture pack sufficient in the typical procedure.	\$4.91
27279	Arthrodesis sacroiliac joint	L037D	RN/LPN/MTA	F	Discharge day management 99238 --12 minutes	12	6	Aligned clinical labor discharge day management time with the work time discharge day code.	\$-2.22
29200	Strapping of chest	L023A	Physical Therapy Aide	NF	Greet patient and provide gowning	3	0	Typically billed with an E/M or other evaluation service	\$-0.69
29240	Strapping of shoulder	L023A	Physical Therapy Aide	NF	Greet patient and provide gowning	3	0	Typically billed with an E/M or other evaluation service	\$-0.69

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommendation or current value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change
29260	Strapping of elbow or wrist	L023A	Physical Therapy Aide	NF	Greet patient and provide gowning	3	0	Typically billed with an E/M or other evaluation service	\$-0.69
29280	Strapping of hand or finger	L023A	Physical Therapy Aide	NF	Greet patient and provide gowning	3	0	Typically billed with an E/M or other evaluation service	\$-0.69
29520	Strapping of hip	L023A	Physical Therapy Aide	NF	Greet patient and provide gowning	3	0	Typically billed with an E/M or other evaluation service	\$-0.69
29530	Strapping of knee	L023A	Physical Therapy Aide	NF	Greet patient and provide gowning	3	0	Typically billed with an E/M or other evaluation service	\$-0.69
29540	Strapping of ankle and/or ft	L023A	Physical Therapy Aide	NF	Greet patient and provide gowning	3	0	Typically billed with an E/M or other evaluation service	\$-0.69
29550	Strapping of toes	L023A	Physical Therapy Aide	NF	Greet patient and provide gowning	3	0	Typically billed with an E/M or other evaluation service	\$-0.69
31627	Navigational bronchoscopy	EF027	table, instrument, mobile	NF		45	30	Standard equipment and time for moderate sedation	\$-0.02
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		45	30	Standard equipment and time for moderate sedation	\$-0.21
		EQ032	IV infusion pump	NF		45	30	Standard equipment and time for moderate sedation	\$-0.09
		L047C	RN/Respiratory Therapist	NF	Prepare and position pt/ monitor pt/ set up IV	2	0	Add-on code; no additional time required to prepare and position patient	\$-0.94
33418	Repair teat mitral valve	L037D	RN/LPN/MTA	F	Discharge day management 99238 --12 minutes	12	0	Aligned clinical labor discharge day management time with the work time discharge day code.	\$-4.44
		L037D	RN/LPN/MTA	F	Discharge day management 99239 -- 15 minutes	0	15	Aligned clinical labor discharge day management time with the work time discharge day code.	\$5.55

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommendation or current value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change
33965	Ecmo/ecls rmvl perph cannula	L051A	RN	F	Schedule space and equipment in facility	0	5	Standard inputs for procedures with 90 day global periods	\$2.55
33966	Ecmo/ecls rmvl prph cannula	L051A	RN	F	Schedule space and equipment in facility	0	5	Standard inputs for procedures with 90 day global periods	\$2.55
36475	Endovenous rf 1st vein	EF019	stretcher chair	NF		30	31	Refined equipment time to conform to clinical labor time.	\$0.01
36476	Endovenous rf vein add-on	EL015	room, ultrasound, general	NF		32	30	Refined equipment time to conform to changes in clinical labor time.	\$-2.80
		EQ215	radiofrequency generator (vascular)	NF		32	30	Refined equipment time to conform to changes in clinical labor time.	\$-0.19
		L054A	Vascular Technologist	NF	Review examination with interpreting MD	1	0	Add-on code; no additional time required for clinical labor tasks associated with digital imaging	\$-0.54
		L054A	Vascular Technologist	NF	Technologist QCs images US machine, checking for all images, reformats, and dose page	1	0	Add-on code; no additional time required for clinical labor tasks associated with digital imaging	\$-0.54
36478	Endovenous laser 1st vein	EF019	stretcher chair	NF		30	31	Refined equipment time to conform to clinical labor time.	\$0.01
36479	Endovenous laser vein addon	EL015	room, ultrasound, general	NF		32	30	Refined equipment time to conform to changes in clinical labor time.	\$-2.80
		EQ160	laser, endovascular ablation (ELVS)	NF		32	30	Refined equipment time to conform to changes in clinical labor time.	\$-0.33
		L054A	Vascular Technologist	NF	Review examination with interpreting MD	1	0	Add-on code; no additional time required for clinical labor tasks associated with digital imaging	\$-0.54

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommendation or current value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change
		L054A	Vascular Technologist	NF	Technologist QCs images US machine, checking for all images, reformats, and dose page	1	0	Add-on code; no additional time required for clinical labor tasks associated with digital imaging	\$-0.54
47383	Perq abltj lvr cryoablation	EF018	stretcher	NF		240	166	Standard equipment and time for moderate sedation	\$-0.39
		EF027	table, instrument, mobile	NF		104	166	Standard equipment and time for moderate sedation	\$0.09
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		164	166	Standard equipment and time for moderate sedation	\$0.03
		EQ032	IV infusion pump	NF		164	166	Standard equipment and time for moderate sedation	\$0.01
		EQ168	light, exam	NF		164	106	Refined equipment time to conform to established policies for non-highly technical equipment.	\$-0.25
52442	Cystourethro w/addl implant	EF027	table, instrument, mobile	NF		0	25	No equipment times were included; aligned equipment time with assist physician time.	\$0.04
		EF031	table, power	NF		0	25	No equipment times were included; aligned equipment time with assist physician time.	\$0.41
		EQ170	light, fiberoptic headlight w-source	NF		0	25	No equipment times were included; aligned equipment time with assist physician time.	\$0.20
		ES018	fiberscope, flexible, cystoscopy	NF		0	25	No equipment times were included; aligned equipment time with assist physician time.	\$1.07

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommendation or current value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		0	25	No equipment times were included; aligned equipment time with assist physician time.	\$3.22
62284	Injection for myelogram	EF018	stretcher	NF		60	48	Refined equipment time to conform to established policies for non-highly technical equipment.	\$-0.06
62302	Myelography lumbar injection	L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	26	13	All clinical labor activities were assigned to L037D. Reassigned imaging tasks to L041B.	\$-4.81
		L041B	Radiologic Technologist	NF	Assist physician in performing procedure	0	13	All clinical labor activities were assigned to L037D. Reassigned imaging tasks to L041B.	\$5.33
62303	Myelography lumbar injection	EF018	stretcher	NF		60	64	Refined equipment time to conform to established policies for non-highly technical equipment.	\$0.02
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	25	13	All clinical labor activities were assigned to L037D. Reassigned imaging tasks to L041B.	\$-4.44
		L041B	Radiologic Technologist	NF	Assist physician in performing procedure	0	12	All clinical labor activities were assigned to L037D. Reassigned imaging tasks to L041B.	\$4.92
62304	Myelography lumbar injection	EF018	stretcher	NF		60	59	Refined equipment time to conform to established policies for non-highly technical equipment.	\$-0.01
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	25	13	All clinical labor activities were assigned to L037D. Reassigned imaging tasks to L041B.	\$-4.44

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommendation or current value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change
		L041B	Radiologic Technologist	NF	Assist physician in performing procedure	0	12	All clinical labor activities were assigned to L037D. Reassigned imaging tasks to L041B.	\$4.92
62305	Myelography lumbar injection	EF018	stretcher	NF		60	64	Refined equipment time to conform to established policies for non-highly technical equipment.	\$0.02
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	30	15	All clinical labor activities were assigned to L037D. Reassigned imaging tasks to L041B.	\$-5.55
		L041B	Radiologic Technologist	NF	Assist physician in performing procedure	0	15	All clinical labor activities were assigned to L037D. Reassigned imaging tasks to L041B.	\$6.15
64561	Implant neuroelectrodes	EQ202	percutaneous neuro test stimulator	NF		0	65	Neuro test stimulator is required to complete Percutaneous implantation of neurostimulator	\$0.17
		SB012	drape, sterile, for Mayo stand	NF		1	0	Duplicative; Item included in percutaneous neuro test stimulation kit (SA022).	\$-1.69
		SG074	steri-strip (6 strip uou)	NF		1	0	Duplicative; Item included in percutaneous neuro test stimulation kit (SA022).	\$-1.12
		SJ043	povidone swabsticks (3 pack uou)	NF		1	0	Duplicative; Item included in percutaneous neuro test stimulation kit (SA022).	\$-0.41
70486	Ct maxillofacial w/o dye	L041B	Radiologic Technologist	NF	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocolled by radiologist	3	2	Standard times for clinical labor tasks associated with digital imaging	\$-0.41

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommendation or current value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change
70487	Ct maxillofacial w/dye	L041B	Radiologic Technologist	NF	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocolled by radiologist	3	2	Standard times for clinical labor tasks associated with digital imaging	\$-0.41
		L046A	CT Technologist	NF	SVC Provide pre-service education/obtain consent	3	2	CT Angiography only requires 2 minutes for this task; maintain consistency within family	\$-0.46
70488	Ct maxillofacial w/o & w/dye	L041B	Radiologic Technologist	NF	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocolled by radiologist	3	2	Standard times for clinical labor tasks associated with digital imaging	\$-0.41
		L046A	CT Technologist	NF	SVC Provide pre-service education/obtain consent	3	2	CT Angiography only requires 2 minutes for this task; maintain consistency within family	\$-0.46
74174	Ct angio abd&pelv w/o&w/dye	L046A	CT Technologist	NF	Availability of prior images confirmed	3	2	Standard times for clinical labor tasks associated with digital imaging	\$-0.46
76641	Ultrasound breast complete	EL015	room, ultrasound, general	NF		30	27	Refined equipment time to conform to established policies for highly technical equipment.	\$-4.21
76642	Ultrasound breast limited	EL015	room, ultrasound, general	NF		28	20	Refined equipment time to conform to established policies for highly technical equipment.	\$-11.21

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		L046A	CT Technologist	NF	Acquire images	15	10	Limited study takes less time to complete than complete study; used ratio of ultrasound abdomen complete and limited to adjust 15 to 10 minutes.	\$-2.30
76942	Echo guide for biopsy	L051B	RN/Diagnostic Medical Sonographer	NF	Availability of prior images confirmed	3	2	Standard times for clinical labor tasks associated with digital imaging	\$-0.51
77061	Breast tomosynthesis uni	L043A	Mammography Technologist	NF	Availability of prior images confirmed	3	2	Standard times for clinical labor tasks associated with digital imaging	\$-0.43
77062	Breast tomosynthesis bi	L043A	Mammography Technologist	NF	Availability of prior images confirmed	3	2	Standard times for clinical labor tasks associated with digital imaging	\$-0.43
77063	Breast tomosynthesis bi	L043A	Mammography Technologist	NF	Federally Mandated MQSA Activities Allocated To Each Mammogram	4	0	Add-on code; no additional time required for this task.	\$-1.72
77085	Dxa bone density study	ER019	densitometry unit, fan beam, DXA (w-computer hardware & software)	NF		38	34	Refined equipment time to conform to changes in clinical labor time.	\$-1.29
		L041B	Radiologic Technologist	NF	Technologist QC's images in PACS, checking all images, reformats, and dose page	6	2	Standard times for clinical labor tasks associated with digital imaging	\$-1.64
77086	Fracture assessment via dxa	ER019	densitometry unit, fan beam, DXA (w-computer hardware & software)	NF		21	19	Refined equipment time to conform to changes in clinical labor time.	\$-0.64

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		L041B	Radiologic Technologist	NF	Technologist QC's images in PACS, checking all images, reformats, and dose page	4	2	Standard times for clinical labor tasks associated with digital imaging	\$-0.82
77300	Radiation therapy dose plan	ED011	computer system, record and verify	NF		5	0	Item was not previously included for this service; rationale for change not provided. See 78 FR 74317 for further discussion.	\$-3.10
77306	Telethx isodose plan simple	ED011	computer system, record and verify	NF		5	0	Item was not previously included for this service; rationale for change not provided. See 78 FR 74317 for further discussion.	\$-3.10
77307	Telethx isodose plan cplx	ED011	computer system, record and verify	NF		5	0	Item was not previously included for this service; rationale for change not provided. See 78 FR 74317 for further discussion.	\$-3.10
88341	Immunohisto antibody slide	EP024	microscope, compound	NF		21	13	Decreased physician work for 88341 to 60% of 88342; same adjustment was made for equipment used by physician.	\$-0.30
		EP110	Freezer	NF		1	0	Indirect Practice Expense. Not individually allocable to a particular patient for a particular service	\$-0.02
		SA117	Universal Detection Kit	NF		0	2	Maintain consistency in the type of universal detection kit with remaining code-sets within this family.	\$8.00
		SL488	UltraView Universal DAB Detection Kit	NF		2	0	Maintain consistency in the type of universal detection kit with remaining code-sets within this family.	\$-20.97
88342	Immunohisto antibody stain	EP110	Freezer	NF		1	0	Indirect Practice Expense. Not individually allocable to a particular patient for a	\$-0.02

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommendation or current value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change
								particular service	
		SA117	Universal Detection Kit	NF		0	2	Maintain consistency in the type of universal detection kit with remaining code-sets within this family.	\$8.00
		SL488	UltraView Universal DAB Detection Kit	NF		2	0	Maintain consistency in the type of universal detection kit with remaining code-sets within this family.	\$-20.97
88344	Immunohisto antibody slide	EP110	Freezer	NF		1	0	Indirect Practice Expense. Not individually allocable to a particular patient for a particular service	\$-0.02
		EP112	Benchmark ULTRA automated slide preparation system	NF		33	30	Multiplex service - 2 stains is typical; since single stains requires 15 minutes, 2 stains requires no more than 30 minutes	\$-1.52
		SA117	Universal Detection Kit	NF		0	4	Maintain consistency in the type of universal detection kit with remaining code-sets within this family.	\$16.00
		SL488	UltraView Universal DAB Detection Kit	NF		2	0	Maintain consistency in the type of universal detection kit with remaining code-sets within this family.	\$-20.97
		SL489	UtraView Universal Alkaline Phosphatase Red Detection Kit	NF		2	0	Maintain consistency in the type of universal detection kit with remaining code-sets within this family.	\$-41.28
88364	Insitu hybridization (fish)	EP024	microscope, compound	NF		37	22	Decreased physician work for 88341 to 60% of 88342; same adjustment was made for equipment used by physician.	\$-0.56

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		EP045	chamber, hybridization	NF		240	0	Add-on code. Base code includes the hybridization chamber, which would be used concurrently for both stains	\$-5.51
		EP054	water bath, FISH procedures (lab)	NF		13	0	Add on code. Water bath is used concurrently for the base code and add-on code	\$-0.09
		EP110	Freezer	NF		1	0	Indirect Practice Expense. Not individually allocable to a particular patient for a particular service	\$-0.02
		L037B	Histotechnologist	NF	Clean room/equipment following procedure (including any equipment maintenance that must be done after the procedure)	0.5	0	Add-on code. Additional clinical labor time for post-service task not required. See preamble.	\$-0.19
		SB023	gloves, non-sterile, nitrile	NF		0.25	0	Add-on code. Gloves are not changed between base code and add-on code	\$-0.05
		SL189	ethanol, 100%	NF		62.5	37.5	No rationale was provided for quantity change relative to current value. Maintaining current value.	\$-0.08
		SL195	kit, FISH paraffin pretreatment	NF		2	1	Maintain consistency in unit of the kit between base code and add-on code. See preamble.	\$-20.85
		SL248	ethanol, 95%	NF		62.5	37.5	No rationale was provided for quantity change relative to current value. Maintaining current value.	\$-0.08
88365	In situ hybridization (fish)	EP110	Freezer	NF		1	0	Indirect Practice Expense. Not individually allocable to a particular patient for a particular service	\$-0.02

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		EP116	VP-2000 Processor	NF		30	0	We are unable to reconcile the new equipment item with the increased technician time. See preamble.	\$-2.90
		SL189	ethanol, 100%	NF		62.5	37.5	No rationale was provided for quantity change relative to current value. Maintaining current value.	\$-0.08
		SL195	kit, FISH paraffin pretreatment	NF		2	1	No rationale was provided for quantity change relative to current value. Maintaining current value.	\$-20.85
		SL248	ethanol, 95%	NF		62.5	37.5	No rationale was provided for quantity change relative to current value. Maintaining current value.	\$-0.08
		SL497	(EBER) DNA Probe Cocktail	NF		1.6	2	Stain needs to be added to the positive control slide and the specimen slide. See preamble.	\$3.43
88366	Insitu hybridization (fish)	EP088	ThermoBrite	NF		2.5	0	This input is not contained within any other code in this family. Maintaining consistency with all other codes within family.	\$-0.05
		EP110	Freezer	NF		1	0	Indirect Practice Expense. Not individually allocable to a particular patient for a particular service	\$-0.02
		EP116	VP-2000 Processor	NF		30	0	We are unable to reconcile the new equipment item with the increased technician time. See preamble.	\$-2.90
		L037B	Histotechnologist	NF	Examine signals in each cell and generate data for the pathologist to interpret	20	15	Refined clinical labor time for this multiplex procedure to reflect efficiencies in examining two stains on a single slide.	\$-1.85

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		SL189	ethanol, 100%	NF		62.5	37.5	No rationale was provided for quantity change relative to current value. Maintaining current value.	\$-0.08
		SL195	kit, FISH paraffin pretreatment	NF		2	1	Maintain consistency in unit of the kit between base code and add-on code. See preamble.	\$-20.85
		SL248	ethanol, 95%	NF		62.5	37.5	No rationale was provided for quantity change relative to current value. Maintaining current value.	\$-0.08
88367	Insitu hybridization auto	EP110	Freezer	NF		1	0	Indirect Practice Expense. Not individually allocable to a particular patient for a particular service	\$-0.02
		SL189	ethanol, 100%	NF		31.25	18.75	No rationale was provided for quantity change relative to current value. Maintaining current value.	\$-0.04
		SL195	kit, FISH paraffin pretreatment	NF		1.4	0.75	No rationale provided for quantity change. See preamble.	\$-13.55
		SL248	ethanol, 95%	NF		31.25	18.75	No rationale was provided for quantity change relative to current value. Maintaining current value.	\$-0.04
88368	Insitu hybridization manual	EP110	Freezer	NF		1	0	Indirect Practice Expense. Not individually allocable to a particular patient for a particular service	\$-0.02
		EP116	VP-2000 Processor	NF		30	0	We are unable to reconcile the new equipment item with the increased technician time. See preamble.	\$-2.90
		SL508	positive control slide (proxy for Kappa Positive Control Slide)	NF		0.5	0.2	Maintain consistency in unit of control slides within family of codes. See preamble.	\$-3.54

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		SL509	positive control slide (proxy for Kappa Negative Control Slide)	NF		0.5	0.2	Maintain consistency in unit of control slides within family of codes. See preamble.	\$-3.54
		SL189	ethanol, 100%	NF		37.5	18.75	No rationale was provided for quantity change relative to current value. Maintaining current value.	\$-0.06
		SL190	ethanol, 70%	NF		12.5	6.25	No rationale was provided for quantity change relative to current value. Maintaining current value.	\$-0.02
		SL191	ethanol, 85%	NF		12.5	6.25	No rationale was provided for quantity change relative to current value. Maintaining current value.	\$-0.02
		SL195	kit, FISH paraffin pretreatment	NF		2	1	No rationale provided for quantity change. See preamble.	\$-20.85
		SL248	ethanol, 95%	NF		37.5	18.75	No rationale was provided for quantity change relative to current value. Maintaining current value.	\$-0.06
		SL498	Kappa Probe Cocktail	NF		40	28	Maintain consistency in unit of probe cocktails within this family of codes. See preamble.	\$-1.14
88369	M/phmtc alysishquant/se miq	EP024	microscope, compound	NF		42	25	Refined equipment time for this multiplex procedure to reflect efficiencies in time when examining two stains on a single slide.	\$-0.64
		EP045	chamber, hybridization	NF		240	0	Add-on code. Base code includes the hybridization chamber, which would be used concurrently for both stains	\$-5.51
		EP054	water bath, FISH procedures (lab)	NF		13	0	Add on code. Water bath is used concurrently for the base code and add-on code	\$-0.09

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		EP110	Freezer	NF		1	0	Indirect Practice Expense. Not individually allocable to a particular patient for a particular service	\$-0.02
		L037B	Histotechnologist	NF	Clean room/equipment following procedure (including any equipment maintenance that must be done after the procedure)	0.5	0	Add-on code. Additional clinical labor time for post-service task not required. See preamble.	\$-0.19
		SB023	gloves, non-sterile, nitrile	NF		0.25	0	Not necessary to change gloves between the slides in the same procedure.	\$-0.05
		SL510	positive control slide (proxy for Lambda Positive Control Slide)	NF		0.5	0.2	Maintain consistency in unit of control slides within family of codes. See preamble.	\$-3.54
		SL511	positive control slide (proxy for Lambda Negative Control Slide)	NF		0.5	0.2	Maintain consistency in unit of control slides within family of codes. See preamble.	\$-3.54
		SL189	ethanol, 100%	NF		37.5	18.75	No rationale was provided for quantity change relative to current value. Maintaining current value.	\$-0.06
		SL195	kit, FISH paraffin pretreatment	NF		2	1	Maintain consistency in unit of the kit between base code and add-on code. See preamble.	\$-20.85
		SL248	ethanol, 95%	NF		37.5	18.75	No rationale was provided for quantity change relative to current value. Maintaining current value.	\$-0.06

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		SL499	Lambda Probe Cocktail	NF		40	28	Maintain consistency in unit of probe cocktails within this family of codes. See preamble.	\$-1.14
88373	M/phmtrc alyshquant/semi	EP024	microscope, compound	NF		42	25	Refined equipment time for this multiplex procedure to reflect efficiencies in time when examining two stains on a single slide.	\$-0.64
		EP045	chamber, hybridization	NF		120	0	Add-on code. Base code includes the hybridization chamber, which would be used concurrently for both stains	\$-2.75
		EP054	water bath, FISH procedures (lab)	NF		7	0	Add on code. Water bath is used concurrently for the base code and add-on code	\$-0.05
		EP110	Freezer	NF		1	0	Indirect Practice Expense. Not individually allocable to a particular patient for a particular service	\$-0.02
		SB023	gloves, non-sterile, nitrile	NF		0.125	0	Not necessary to change gloves between the slides in the same procedure.	\$-0.02
		SL189	ethanol, 100%	NF		31.25	18.75	No rationale was provided for quantity change relative to current value. Maintaining current value.	\$-0.04
		SL195	kit, FISH paraffin pretreatment	NF		1.4	0.75	Maintain consistency in unit of the kit between base code and add-on code. See preamble.	\$-13.55
		SL248	ethanol, 95%	NF		31.25	18.75	No rationale was provided for quantity change relative to current value. Maintaining current value.	\$-0.04
88374	M/phmtrc alyshquant/semi	EP110	Freezer	NF		1	0	Indirect Practice Expense. Not individually allocable to a particular patient for a particular service	\$-0.02

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		SL030	cover slip, glass	NF		2.8	1.4	Quantity of slides required for this multiplex procedure does not differ from the single procedure (only number of stains per slide differs).	\$-0.11
		SL189	ethanol, 100%	NF		31.25	18.75	No rationale was provided for quantity change relative to current value. Maintaining current value.	\$-0.04
		SL195	kit, FISH paraffin pretreatment	NF		1.4	0.75	Maintain consistency in unit of the kit between base code and add-on code. See preamble.	\$-13.55
		SL196	kit, HER-2/neu DNA Probe	NF		2.4	1	A single kit is required for this procedure which involves a single specimen with one stain.	\$-147.00
		SL248	ethanol, 95%	NF		31.25	18.75	No rationale was provided for quantity change relative to current value. Maintaining current value.	\$-0.04
88377	M/phmtrc alysisquant/semi	EP110	Freezer	NF		1	0	Indirect Practice Expense. Not individually allocable to a particular patient for a particular service	\$-0.02
		EP116	VP-2000 Processor	NF		30	0	We are unable to reconcile the new equipment item with the increased technician time. See preamble.	\$-2.90
		L037B	Histotechnologist	NF	Signal Enumeration: Count signals in malignant cells and generate data for pathologist to interpret	24	18	Refined clinical labor time for this multiplex procedure to reflect efficiencies in examining two stains on a single slide.	\$-2.22
		SL184	slide, negative control, Her-2	NF		0.5	0.2	Maintain consistency in unit of control slides within family of codes. See preamble.	\$-8.82

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		SL185	slide, positive control, Her-2	NF		0.5	0.2	Maintain consistency in unit of control slides within family of codes. See preamble.	\$-8.82
		SL189	ethanol, 100%	NF		37.5	18.75	No rationale was provided for quantity change relative to current value. Maintaining current value.	\$-0.06
		SL190	ethanol, 70%	NF		12.5	6.25	No rationale was provided for quantity change relative to current value. Maintaining current value.	\$-0.02
		SL191	ethanol, 85%	NF		12.5	6.25	No rationale was provided for quantity change relative to current value. Maintaining current value.	\$-0.02
		SL195	kit, FISH paraffin pretreatment	NF		2	1	Maintain consistency in unit of the kit between base code and add-on code. See preamble.	\$-20.85
		SL196	kit, HER-2/neu DNA Probe	NF		3	1	A single kit is required for this procedure which involves a single specimen with one stain.	\$-210.00
		SL248	ethanol, 95%	NF		37.5	18.75	No rationale was provided for quantity change relative to current value. Maintaining current value.	\$-0.06
88380	Microdissection laser	EP087	instrument, microdissection (Veritas)	NF		34	32	Since physician is doing this task, equipment time was calculated by summing physician intraservice time, time to set up machine, and time to clean machine.	\$-1.36

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		L045A	Cytotechnologist	NF	Dispose of razor blade, Cap tube and vortex specimens. Visually inspect tube to make sure microdissected material are at the bottom of tube.	3	0	Included in clinical labor task "clean room, equipment, and supplies"	\$-1.35
		L045A	Cytotechnologist	NF	Turn on dissecting microscope, place slide on scope, remove razor blade from box. Microdissect tissue within etched area, while viewing slide under dissecting scope, place tissue into cap of collection tube with blade. Repeat	18	0	Work vignette indicates that the microdissection is performed by the pathologist	\$-8.10
88381	Microdissection manual	SL085	label for microscope slides	NF		4	9	9 slides is typical; 9 labels are required	\$+0.15
93312	Echo transesophageal	ED021	computer, desktop, w-monitor	NF		91	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.90
		ED034	video SVHS VCR (medical grade)	NF		43	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.21
		ED036	video printer, color (Sony medical grade)	NF		57	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.61
		EF027	table, instrument, mobile	NF		105	92	Standard equipment and time for moderate sedation	\$-0.02

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		EL016	room, ultrasound, vascular	NF		57	43	Refined equipment time to conform to established policies for highly technical equipment.	\$-24.75
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		105	92	Standard equipment and time for moderate sedation	\$-0.18
		EQ032	IV infusion pump	NF		0	92	Standard equipment and time for moderate sedation	\$0.58
		L037D	RN/LPN/MTA	NF	Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue	3	1	Standard times for clinical labor tasks associated with digital imaging	\$-0.74
		L050A	Cardiac Sonographer	NF	Clean scope	0	10	Time for cleaning probes moved from activity “clean surgical instrument package” to “clean scope”. 10 minutes unchanged	\$5.00
		L050A	Cardiac Sonographer	NF	Clean surgical instrument package	10	0	Time for cleaning probes moved from activity “clean surgical instrument package” to “clean scope”. 10 minutes unchanged	\$-5.00
		L050A	Cardiac Sonographer	NF	Process data: measure, record, preliminary findings	8	0	Standard times for clinical labor tasks associated with digital imaging	\$-4.00
		L050A	Cardiac Sonographer	NF	Review images with MD	0	2	Standard times for clinical labor tasks associated with digital imaging	\$1.00

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		L050A	Cardiac Sonographer	NF	Technologist QC's images in PACS, checking all images, reformats, and dose page	5	2	Standard times for clinical labor tasks associated with digital imaging	\$-1.50
		SB026	gown, patient	NF		1	0	Duplicative; items are included in pack, minimum multi-specialty visit (SA048)	\$-0.53
		SB036	paper, exam table	NF		7	0	Duplicative; items are included in pack, minimum multi-specialty visit (SA048)	\$-0.10
		SB037	pillow case	NF		1	0	Duplicative; items are included in pack, minimum multi-specialty visit (SA048)	\$-0.31
93314	Echo transesophageal	ED021	computer, desktop, w-monitor	NF		61	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.60
		ED034	video SVHS VCR (medical grade)	NF		53	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.26
		ED036	video printer, color (Sony medical grade)	NF		67	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.71
		EF027	table, instrument, mobile	NF		115	92	Standard equipment and time for moderate sedation	\$-0.03
		EL016	room, ultrasound, vascular	NF		67	43	Refined equipment time to conform to changes in clinical labor time; See preamble.	\$-42.42
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		115	92	Standard equipment and time for moderate sedation	\$-0.32
		EQ032	IV infusion pump	NF		0	92	Standard equipment and time for moderate sedation	\$0.58

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		L037D	RN/LPN/MTA	NF	Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue	3	1	Standard times for clinical labor tasks associated with digital imaging	\$-0.74
		L050A	Cardiac Sonographer	NF	Assist physician in performing procedure (acquire ultrasound data)	40	30	CPT code 93314 is a less involved service than CPT code 93312, clinical labor time would not be higher. See preamble.	\$-5.00
		L050A	Cardiac Sonographer	NF	Clean scope	0	10	Time for cleaning probes moved from activity "clean surgical instrument package" to "clean scope". 10 minutes unchanged	\$5.00
		L050A	Cardiac Sonographer	NF	Clean surgical instrument package	10	0	Time for cleaning probes moved from activity "clean surgical instrument package" to "clean scope". 10 minutes unchanged	\$-5.00
		L050A	Cardiac Sonographer	NF	Process data: measure, record, preliminary findings	8	0	Standard times for clinical labor tasks associated with digital imaging	\$-4.00
		L050A	Cardiac Sonographer	NF	Review images with MD	0	2	Standard times for clinical labor tasks associated with digital imaging	\$1.00
		L050A	Cardiac Sonographer	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page	5	2	Standard times for clinical labor tasks associated with digital imaging	\$-1.50

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		L051A	RN	NF	Assist physician/moderate sedation (% of physician time)	40	30	CPT code 93314 is a less involved service than CPT code 93312, clinical labor time would not be higher. See preamble.	\$-5.10
		SB026	gown, patient	NF		1	0	Duplicative; items are included in pack, minimum multi-specialty visit (SA048)	\$-0.53
		SB036	paper, exam table	NF		7	0	Duplicative; items are included in pack, minimum multi-specialty visit (SA048)	\$-0.10
		SB037	pillow case	NF		1	0	Duplicative; items are included in pack, minimum multi-specialty visit (SA048)	\$-0.31
93320	Doppler echo exam heart	ED021	computer, desktop, w-monitor	NF		5	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.05
93321	Doppler echo exam heart	ED021	computer, desktop, w-monitor	NF		2	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.02
93325	Doppler color flow add-on	ED021	computer, desktop, w-monitor	NF		2	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.02
93702	Bis xtracell fluid analysis	L037D	RN/LPN/MTA	NF	Results are uploaded from the device into the analysis software and a report is generated and printed for physician review.	2	0	Included as an automatic process for the new device.	\$-0.74
93880	Extracranial bilat study	ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	\$-2.16

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommendation or current value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change
		L054A	Vascular Technologist	NF	Technologist reviews & optimizes all duplex images; reviews & optimizes spectrum analysis measuring velocities & assuring proper angle acquisition. Compiles findings with sufficient data for physician review & diagnosis.	8	2	Standard times for clinical labor tasks associated with digital imaging	\$-3.24
93882	Extracranial uni/ltd study	ED021	computer, desktop, w-monitor	NF		4	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.04
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	\$-2.16
		L054A	Vascular Technologist	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page	5	2	Standard times for clinical labor tasks associated with digital imaging	\$-1.62
93886	Intracranial complete study	ED021	computer, desktop, w-monitor	NF		7	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.07
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	\$-2.16

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommendation or current value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change
		L054A	Vascular Technologist	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page	8	2	Standard times for clinical labor tasks associated with digital imaging	\$-3.24
93888	Intracranial limited study	ED021	computer, desktop, w-monitor	NF		4	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.04
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	\$-2.16
		L054A	Vascular Technologist	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page	4	2	Standard times for clinical labor tasks associated with digital imaging	\$-1.08
93925	Lower extremity study	ED021	computer, desktop, w-monitor	NF		7	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.07
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.11
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	\$-2.16

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommendation or current value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change
		L054A	Vascular Technologist	NF	Technologist reviews & optimizes all duplex images; reviews & optimizes spectrum analysis measuring velocities & assuring proper angle acquisition. Compiles findings with sufficient data for physician review & diagnosis.	8	2	Standard times for clinical labor tasks associated with digital imaging	\$-3.24
93926	Lower extremity study	ED021	computer, desktop, w-monitor	NF		4	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.04
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	\$-2.16

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommendation or current value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change
		L054A	Vascular Technologist	NF	Technologist reviews & optimizes all duplex images; reviews & optimizes spectrum analysis measuring velocities & assuring proper angle acquisition. Compiles findings with sufficient data for physician review & diagnosis.	5	2	Standard times for clinical labor tasks associated with digital imaging	\$-1.62
93930	Upper extremity study	ED021	computer, desktop, w-monitor	NF		7	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.07
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	\$-2.16
93931	Upper extremity study	ED021	computer, desktop, w-monitor	NF		4	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.04
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	\$-2.16
93970	Extremity study	ED021	computer, desktop, w-monitor	NF		7	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.07

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommendation or current value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	\$-2.16
93971	Extremity study	ED021	computer, desktop, w-monitor	NF		4	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.04
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	\$-2.16
93975	Vascular study	ED021	computer, desktop, w-monitor	NF		7	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.07
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	\$-2.16

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommendation or current value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change
		L054A	Vascular Technologist	NF	Technologist reviews & optimizes all duplex images; reviews & optimizes spectrum analysis measuring velocities & assuring proper angle acquisition. Compiles findings with sufficient data for physician review & diagnosis.	8	2	Standard times for clinical labor tasks associated with digital imaging	\$-3.24
93976	Vascular study	ED021	computer, desktop, w-monitor	NF		4	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.04
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	\$-2.16

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommendation or current value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change
		L054A	Vascular Technologist	NF	Technologist reviews & optimizes all duplex images; reviews & optimizes spectrum analysis measuring velocities & assuring proper angle acquisition. Compiles findings with sufficient data for physician review & diagnosis.	5	2	Standard times for clinical labor tasks associated with digital imaging	\$-1.62
93978	Vascular study	ED021	computer, desktop, w-monitor	NF		7	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.07
		ED021	computer, desktop, w-monitor	NF		7	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.07
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	\$-2.16
93979	Vascular study	ED021	computer, desktop, w-monitor	NF		4	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.04
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	\$-2.16
93990	Doppler flow testing	ED021	computer, desktop, w-	NF		4	0	Duplicative; item is in vascular ultrasound room	\$-0.04

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommendation or current value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change
			monitor					(EL016)	
		ED036	video printer, color (Sony medical grade)	NF		4	0	Duplicative; item is in vascular ultrasound room (EL016)	\$-0.04
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	\$-2.16
95971	Analyze neurostim simple	EF023	table, exam	NF		27	33	Include 100% of intraservice time for equipment even when clinical labor assist time is 66% of physician time.	\$0.02
		EQ209	programmer, neurostimulator (w-printer)	NF		27	33	Include 100% of intraservice time for equipment even when clinical labor assist time is 66% of physician time.	\$0.04
95972	Analyze neurostim complex	EF023	table, exam	NF		30	36	Include 100% of intraservice time for equipment even when clinical labor assist time is 66% of physician time.	\$0.02
		EQ209	programmer, neurostimulator (w-printer)	NF		30	36	Include 100% of intraservice time for equipment even when clinical labor time is 66% of assist physician time.	\$0.04
96127	Brief emotional/behavioral assessment	L026A	Medical/Technical Assistant	NF	Scoring completed behavior assessment tool	15	7	Instructions suggest that it typically takes 7 minutes for scoring the tests included as standardized tests for this procedure.	\$-2.08
97605	Neg press wound tx <=50 cm	EF014	light, surgical	NF		28	25	Refined equipment time to conform to changes in clinical labor time.	\$-0.03
		EF031	table, power	NF		28	25	Refined equipment time to conform to changes in clinical labor time.	\$-0.05

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommendation or current value (min or qty)	CMS Refinement (min or qty)	Comment	Direct Costs Change
		L037D	RN/LPN/MTA	NF	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions	5	2	Intraservice clinical labor time also includes time for wound checking	\$-1.11
97606	Neg press wound tx >50 cm	EF014	light, surgical	NF		38	35	Refined equipment time to conform to changes in clinical labor time.	\$-0.03
		EF031	table, power	NF		38	35	Refined equipment time to conform to changes in clinical labor time.	\$-0.05
		L037D	RN/LPN/MTA	NF	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions	5	2	Intraservice clinical labor time also includes time for wound checking	\$-1.11
		EF031	table, power	NF		38	35	Refined equipment time to conform to changes in clinical labor time.	\$-0.05
		L037D	RN/LPN/MTA	NF	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions	5	2	Intraservice clinical labor time also includes time for wound checking	\$-1.11
99490	Chron care mgmt srvc 20 min Chron care mgmt srvc 20 min	L051A	RN	NF	Care management activities performed by clinical staff	60	0	20 minutes RN/LPN/MTA time reflects the typical service; see CCM preamble.	\$-30.60
		L037D	RN/LPN/MTA	NF	Care management activities performed by clinical staff	0	20	20 minutes RN/LPN/MTA time reflects the typical service; see CCM preamble.	\$7.40

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iii. Procedures Subject to the Cap on Imaging Codes Defined by Section 5102(b) of the DRA

We are proposing to add the new codes to the list of procedures subject to the DRA cap, effective January 1, 2015. The codes are: (76641 (Ultrasound breast complete), 76642 (Ultrasound breast limited), 77085 (Dxa bone density study), 77086 (Fracture assessment via dxa), 77387 (Guidance for radiaj tx dlvr), G6001 (Stereoscopic x-ray guidance), and G6002 (Echo guidance radiotherapy). These codes, which are new for CY 2015, replace codes deleted

for CY 2015 that were subject to the cap, and meet the definition of imaging under section 5102(b) of the DRA. These codes are being added on an interim final basis and are open to public comment in this final rule with comment period.

d. Establishing CY 2015 Interim Final Malpractice RVUs

According to our malpractice methodology discussed in section II.C, we are assigning malpractice RVUs for CY 2015 new, revised, and potentially misvalued codes by utilizing a crosswalk to a source code with a similar malpractice risk. We have

reviewed the RUC recommended malpractice source code crosswalks for CY 2015 new, revised, and potentially misvalued codes, and we are accepting all of them on an interim final basis for CY 2015. For G-codes that we are creating, we are also assigning source code crosswalks to similar codes.

Table 32 lists the CY 2015 HCPCS codes and their respective source codes used to set the interim final CY 2015 MP RVUs. The MP RVUs for these services are reflected in Addendum B of this CY 2015 PFS final rule with comment period.

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TABLE 32: Crosswalk for Establishing CY 2015 New/Revised/Potentially Misvalued Codes Malpractice RVUs

CY 2015 New, Revised or Misvalued Code		Malpractice Risk Factor Crosswalk Code	
20604	Drain/inj joint/bursa w/us	20600	Drain/inject joint/bursa
20606	Drain/inj joint/bursa w/us	20605	Drain/inject joint/bursa
20611	Drain/inj joint/bursa w/us	20610	Drain/inject joint/bursa
20983	Ablate bone tumor(s) perq	20982	Ablate bone tumor(s) perq
21811	Optx of rib fx w/fixj scope	21805	Treatment of rib fracture
21812	Treatment of rib fracture	21805	Treatment of rib fracture
21813	Treatment of rib fracture	21805	Treatment of rib fracture
22510	Perq cervicothoracic inject	22520	Percut vertebroplasty thor
22511	Perq lumbosacral injection	22521	Percut vertebroplasty lumb
22512	Vertebroplasty addl inject	22522	Percut vertebroplasty addl
22513	Perq vertebral augmentation	22523	Percut kyphoplasty thor
22514	Perq vertebral augmentation	22524	Percut kyphoplasty lumbar
22515	Perq vertebral augmentation	22525	Percut kyphoplasty add-on
22858	Second level cer discectomy	22856	Cerv artific discectomy
27279	Arthrodesis sacroiliac joint	62287	Percutaneous discectomy
33270	Ins/rep subq defibrillator	33249	Nsert pace-defib w/lead
33271	Insj subq impltbl dfb elctrd	33216	Insert 1 electrode pm-defib
33272	Rmvl of subq defibrillator	33244	Remove eltrd transven
33273	Repos prev impltbl subq dfb	33215	Reposition pacing-defib lead
33418	Repair tcvt mitral valve	92987	Revision of mitral valve
33419	Repair tcvt mitral valve	92987	Revision of mitral valve
33946	Ecmo/ecls initiation venous	33960	External circulation assist
33947	Ecmo/ecls initiation artery	33960	External circulation assist
33948	Ecmo/ecls daily mgmt-venous	33961	External circulation assist
33949	Ecmo/ecls daily mgmt artery	33961	External circulation assist
33951	Ecmo/ecls insj prph cannula	36822	Insertion of cannula(s)
33952	Ecmo/ecls insj prph cannula	36822	Insertion of cannula(s)
33953	Ecmo/ecls insj prph cannula	36822	Insertion of cannula(s)
33954	Ecmo/ecls insj prph cannula	36822	Insertion of cannula(s)
33955	Ecmo/ecls insj ctr cannula	33981	Replace vad pump ext
33956	Ecmo/ecls insj ctr cannula	33981	Replace vad pump ext
33957	Ecmo/ecls repos perph cnula	33981	Replace vad pump ext
33958	Ecmo/ecls repos perph cnula	33981	Replace vad pump ext
33959	Ecmo/ecls repos perph cnula	33981	Replace vad pump ext
33962	Ecmo/ecls repos perph cnula	33981	Replace vad pump ext
33963	Ecmo/ecls repos perph cnula	33981	Replace vad pump ext
33964	Ecmo/ecls repos perph cnula	33981	Replace vad pump ext
33965	Ecmo/ecls rmvl perph cannula	33981	Replace vad pump ext
33966	Ecmo/ecls rmvl prph cannula	33981	Replace vad pump ext
33969	Ecmo/ecls rmvl perph cannula	33971	Aortic circulation assist
33984	Ecmo/ecls rmvl prph cannula	33971	Aortic circulation assist
33985	Ecmo/ecls rmvl ctr cannula	33977	Remove ventricular device
33986	Ecmo/ecls rmvl ctr cannula	33977	Remove ventricular device

CY 2015 New, Revised or Misvalued Code		Malpractice Risk Factor Crosswalk Code	
33987	Artery expos/graft artery	33530	Coronary artery bypass/reop
33988	Insertion of left heart vent	33530	Coronary artery bypass/reop
33989	Removal of left heart vent	33257	Ablate atria lmted add-on
37218	Stent placemt ante carotid	37217	Stent placemt retro carotid
43180	Esophagoscopy rigid trnso	43130	Removal of esophagus pouch
44381	Small bowel endoscopy br/wa	45340	Sig w/balloon dilation
44384	Small bowel endoscopy	44383	Ileoscopy w/stent
45346	Sigmoidoscopy w/ablation	45339	Sigmoidoscopy w/ablate tumr
45347	Sigmoidoscopy w/plcmt stent	45345	Sigmoidoscopy w/stent
45349	Sigmoidoscopy w/resection	43236	Uppr gi scope w/submuc inj
45350	Sgmdsc w/band ligation	45332	Sigmoidoscopy w/fb removal
45388	Colonoscopy w/ablation	45383	Lesion removal colonoscopy
45389	Colonoscopy w/stent plcmt	45387	Colonoscopy w/stent
45390	Colonoscopy w/resection	45385	Lesion removal colonoscopy
45393	Colonoscopy w/decompression	45379	Colonoscopy w/fb removal
45398	Colonoscopy w/band ligation	45379	Colonoscopy w/fb removal
47383	Perq abltj lvr cryoablation	47382	Percut ablate liver rf
52441	Cystourethro w/implant	52282	Cystoscopy implant stent
52442	Cystourethro w/addl implant	52282	Cystoscopy implant stent
62302	Myelography lumbar injection	62284	Injection for myelogram
62303	Myelography lumbar injection	62284	Injection for myelogram
62304	Myelography lumbar injection	62284	Injection for myelogram
62305	Myelography lumbar injection	62284	Injection for myelogram
64486	Tap block unil by injection	64447	N block inj fem single
64487	Tap block uni by infusion	64448	N block inj fem cont inf
64488	Tap block bi injection	64447	N block inj fem single
64489	Tap block bi by infusion	64448	N block inj fem cont inf
66179	Aqueous shunt eye w/o graft	66180	Implant eye shunt
66184	Revision of aqueous shunt	66185	Revise eye shunt
76641	Ultrasound breast complete	76645	Us exam breast(s)
76642	Ultrasound breast limited	76645	Us exam breast(s)
77063	Breast tomosynthesis bi	77057	Mammogram screening
77085	Dxa bone density study	77080	Dxa bone density axial
77086	Fracture assessment via dxa	77082	Dxa bone density vert fx
77306	Teletx isodose plan simple	77305	Teletx isodose plan simple
77307	Teletx isodose plan cplx	77315	Teletx isodose plan complex
77316	Brachytx isodose plan simple	77326	Brachytx isodose calc simp
77317	Brachytx isodose intermed	77327	Brachytx isodose calc interm
77318	Brachytx isodose complex	77328	Brachytx isodose plan compl
88341	Immunohisto antibody slide	88342	Immunohisto antibody slide
88344	Immunohisto antibody slide	88342	Immunohisto antibody slide
88364	Insitu hybridization (fish)	88365	Insitu hybridization (fish)
88366	Insitu hybridization (fish)	88365	Insitu hybridization (fish)
88369	M/phmtrc alyshquant/semi	88368	Insitu hybridization manual
88373	M/phmtrc alyshquant/semi	88367	Insitu hybridization auto
88374	M/phmtrc alyshquant/semi	88367	Insitu hybridization auto

CY 2015 New, Revised or Misvalued Code		Malpractice Risk Factor Crosswalk Code	
88377	M/phmtrc alyshquant/semi	88368	Insitu hybridization manual
91200	Liver elastography	91132	Electrogastrography
92145	Corneal hysteresis deter	76514	Echo exam of eye thickness
93260	Prgrmg dev eval impltbl sys	93282	Icd device progr eval 1 sngl
93261	Interrogate subq defib	93289	Icd device interrogate
93355	Echo transesophageal (tee)	93312	Echo transesophageal
93644	Electrophysiology evaluation	93642	Electrophysiology evaluation
93702	Bis xtracell fluid analysis	93701	Bioimpedance cv analysis
93895	Carotid intima atheroma eval	93882	Extracranial uni/ltd study
96127	Brief emotional/behav asmt	96110	Developmental screen
99184	Hypothermia ill neonate	99291	Critical care first hour
99490	Chron care mgmt srv 20 min	99212	Office/outpatient visit est
G0277	Hbot, full body chamber, 30m	99183	Hyperbaric oxygen therapy
G0279	tomosynthesis, mammo scre	77055	Mammogram one breast
G0473	Face-to-face behavioral counseling for obesity, group (2-10), 30 minutes	G0477	Behavior counsel obesity 15m

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H. Chronic Care Management (CCM)

As we discussed in the CY 2013 PFS final rule with comment period, we are committed to supporting primary care and we have increasingly recognized care management as one of the critical components of primary care that contributes to better health for individuals and reduced expenditure growth (77 FR 68978). Accordingly, we have prioritized the development and implementation of a series of initiatives designed to improve payment for, and encourage long-term investment in, care management services. These initiatives include the following programs and demonstrations:

- The Medicare Shared Savings Program (described in “Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule,” which appeared in the November 2, 2011 **Federal Register** (76 FR 67802)).
- The testing of the Pioneer ACO model, designed for experienced health care organizations (described on the Centers for Medicare and Medicaid Innovation’s (Innovation Center’s) Web site at <http://innovation.cms.gov/initiatives/Pioneer-ACO-Model/index.html>).
- The testing of the Advance Payment ACO model, designed to support organizations participating in the Medicare Shared Savings Program (described on the Innovation Center’s Web site at <http://innovation.cms.gov/initiatives/Advance-Payment-ACO-Model/>).

- The Primary Care Incentive Payment (PCIP) Program (described on the CMS Web site at www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/PCIP-2011-Payments.pdf).

- The patient-centered medical home model in the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration designed to test whether the quality and coordination of health care services are improved by making advanced primary care practices more broadly available (described on the CMS Web site at www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/mapcpdemo_Factsheet.pdf).

- The Federally Qualified Health Center (FQHC) Advanced Primary Care Practice demonstration (described on the CMS Web site at http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/Downloads/FQHC_APCP_Demo_FAQsOct2011.pdf and the Innovation Center’s Web site at www.innovations.cms.gov/initiatives/FQHCs/index.html).

- The Comprehensive Primary Care (CPC) initiative (described on the Innovation Center’s Web site at <http://innovations.cms.gov/initiatives/Comprehensive-Primary-Care-Initiative/index.html>). The CPC initiative is a multi-payer initiative fostering collaboration between public and private health care payers to strengthen primary care in certain markets across the country.

In addition, HHS leads a broad initiative focused on optimizing health and quality of life for individuals with

multiple chronic conditions. HHS’s Strategic Framework on Multiple Chronic Conditions outlines specific objectives and strategies for HHS and private sector partners centered on strengthening the health care and public health systems; empowering the individual to use self-care management with the assistance of a healthcare provider who can assess the patient’s health literacy level; equipping care providers with tools, information, and other interventions; and supporting targeted research about individuals with multiple chronic conditions and effective interventions. Further information on this initiative is available on the HHS Web site at <http://www.hhs.gov/ash/initiatives/mcc/index.html>.

In coordination with all of these initiatives, we also have continued to explore potential refinements to the PFS that would appropriately value care management within Medicare’s statutory structure for fee-for-service physician payment and quality reporting. For example, in the CY 2013 PFS final rule with comment period, we adopted a policy to pay separately for care management involving the transition of a beneficiary from care furnished by a treating physician during a hospital stay to care furnished by the beneficiary’s primary physician in the community (77 FR 68978 through 68993).

In the CY 2014 PFS final rule with comment period, we finalized a policy to pay separately for care management services furnished to Medicare beneficiaries with two or more chronic

conditions beginning in CY 2015 (78 FR 74414).

1. Valuation of CCM Services—GXXX1

CCM is a unique PFS service designed to pay separately for non-face-to-face care coordination services furnished to Medicare beneficiaries with multiple chronic conditions. (See 78 FR 74414 for a more thorough discussion of the beneficiaries for whom this service may be billed and the scope of service elements.) In the CY 2014 PFS final rule with comment period, we indicated that, to recognize the additional resources required to furnish CCM services to patients with multiple chronic conditions, we were creating the following code to use for reporting this service (78 FR 74422):

- **GXXX1** Chronic care management services furnished to patients with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; 20 minutes or more; per 30 days.

Although this service is unique in that it was created to separately pay for care management services, other codes include care management components. To value CCM, we compared it to other codes that involve care management. In doing so, we concluded that the CCM services were similar in work (time and intensity) to that of the non-face-to-face portion of the lower level code for transitional care management (TCM) services (CPT code 99495 (Transitional Care Management Services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge Medical decision making of at least moderate complexity during the service period face-to-face visit, within 14 calendar days of discharge)). Accordingly, we based the proposed inputs on the non-face-to-face portion of CPT code 99495.

Specifically, we proposed a work RVU for GXXX1 of 0.61, which is the portion of the work RVU for CPT code 99495 that remains after subtracting the work attributable to the face-to-face visit. (CPT code 99214 (Office/outpatient visit est) was used to value CPT code 99495, which has a work RVU of 1.50). Similarly, we proposed a work time of 15 minutes for HCPCS code GXXX1 for CY 2015 based on the time attributable to the non-face-to-face portion of CPT 99495.

For direct PE inputs, we proposed 20 minutes of clinical labor time. As established in the CY 2014 PFS final

rule with comment period, in order to bill for this code, at least 20 minutes of CCM services must be furnished during the 30-day billing interval (78 FR 74422). Based upon input from stakeholders and the nature of care management services, we believed that many aspects of this service will be provided by clinical staff, and thus, clinical staff would be involved in the typical service for the full 20 minutes. CPT code 99495 has 45 minutes of non-face-to-face clinical labor time and we assumed the typical case for CCM would involve 20 minutes based upon the code descriptor and a broad eligible population that would require limited monthly services. The proposed CY 2015 direct PE input database reflected the input of 20 minutes of clinical labor time and is available on the CMS Web site under the supporting data files for the CY 2015 PFS proposed rule at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>. The resulting proposed PE RVUs were 0.57 for CCM furnished in non-facility locations and 0.26 for CCM furnished in a facility.

The proposed MP RVU of 0.04 was calculated using the weighted risk factors for the specialties that we believed would furnish this service. We believed the proposed malpractice risk factor would appropriately reflect the relative malpractice risk associated with furnishing CCM services.

We received many public comments on our proposed valuation. In general, the commenters commended CMS for ongoing recognition of the value of non-face-to-face time expended by physicians and staff to improve outcomes for beneficiaries with chronic conditions, and the proposal to pay separately for the non-face-to-face services. However, the commenters generally believed the proposed valuation for CCM services underestimated the resources involved with complex beneficiaries, and recommended various alternatives for valuing the services. We summarize these comments in the following paragraphs.

Comment: Several commenters noted that the CPT Editorial Panel created a new code for CY 2015 that is extremely similar to the G-code we developed to report these services. These commenters suggested that we use the new CPT code 99490 (Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements:

- Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient;
- Chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline;
- Comprehensive care plan established, implemented, revised, or monitored).

Many of these commenters expressed a preference for the “per calendar month” used in the CPT descriptor to the “per 30 days” used in the G-code. The commenters said a calendar month rather than 30 days would be less complex administratively.

Response: It is our preference to use CPT codes unless Medicare has a programmatic need that is not met by the CPT coding structure. Accordingly, in the CY 2014 final rule with comment period we indicated that we would consider using a CPT code if one was created that reflected the service we were describing with the G-code. We believe that the new CPT code 99490 appropriately describes CCM services for Medicare beneficiaries.

We had used 30 days rather than a calendar month as the service period for the G-code so that the number of days in the service period would not vary based upon when CCM services were initiated for a given period. For example, if the services were initiated near the end of a calendar month, using the CPT code’s period of “per calendar month” would make it harder for the practitioner to meet the required minimum time for the month and be able to bill CMM for that month.

However, after learning about the administrative difficulties that the 30-day period would create, we believe that the calendar month creates a reasonable period. Accordingly, we will adopt CPT code 99490 for Medicare CCM services, effective January 1, 2015 instead of the G code.

Comment: Several commenters suggested alternative approaches to the use of codes that describe CCM services. For example, one commenter said that the code should be for one year, with average of 20 minutes per month across the year. Another commenter was concerned about how the 20 minutes of care per month per patient will be calculated, because some patients (those whose condition is less well controlled) will demand more attention and care than average patients, while those whose condition is well controlled might require very little attention. This commenter suggested that a reasonable solution would be for the care minutes per patient per month to be calculated as an average across a number of CCM

patients. The commenter added that for patients entering and exiting mid-month, the average minutes of care could be calculated on a pro rata basis which adjusts for the partial months they are eligible for CCM services. Several other commenters said that CMS should use a capitated payment methodology for CCM services in the long run, but supported CCM services using the CPT codes as valued by the RUC as a short-term transitional strategy until CMS is able to expand the per beneficiary per month care management fee under CMS's primary care demonstration initiatives to all physicians. Others commented similarly that the long-term goal is capitated payments like the demonstrations/ models that better encourage population-based health management and reducing utilization.

Several commenters submitted recommendations for valuation based on their experience in CMS's Patient-Centered Medical Home multipayer initiative. Assuming CCM services are furnished by a care manager receiving an annual salary of \$150,000, and taking into account a commonly accepted patient to care manager ratio of 1:150, these commenters believed that under the proposed payment rate, the average service time possible would be a ceiling of 23 minutes (not a floor of 20 minutes). Based on one tracking study of care manager activity in minutes per patient per month, they believed complex care management would require 42 minutes of face-to-face and non-face-to-face time per month. Assuming the same care manager salary and patient load, the commenters asserted that the monthly payment amount necessary to provide this amount of care would be \$83 per beneficiary per month.

Response: Our proposal to pay separately for these services is part of a broader series of potential refinements to the PFS that appropriately value care management within Medicare's statutory structure for fee-for-service physician payment. We do not have statutory authority to base payment under the PFS on a recurring per beneficiary per month basis. The PFS is limited to a fee-for-service model at present, and as such we do not use capitated payment for services that may or may not be furnished in a given month. We refer the commenter and other interested stakeholders to the preceding paragraphs that describe a broader set of initiatives that are designed to improve payment for, and encourage long-term investment in, care management services, including a

variety of CMS and HHS programs and demonstrations.

Comment: Many commenters recommended a higher valuation for CCM services than was proposed, with some commenters providing specific suggestions as to changes in inputs and others simply asserting that a higher payment was appropriate or necessary to achieve access or the desired benefit. One commenter recommended a payment of \$75 but did not provide supporting information. Several other commenters recommended that CMS adopt the RUC-recommended values for CPT code 99490 (work time of 30 minutes, work RVU of 1.0, and 60 minutes of clinical labor time). Several commenters believed CMS should adopt the work, PE and MP RVUs for CPT code 99495, with one commenter suggesting that CMS crosswalk the PE and MP RVU from the TCM code and not just the work RVU from the code in order to equalize payment for the CCM code with a per beneficiary per month payment that is made for similar services through a state Medicaid program. Another commenter pointed out that the proposed combined MP and PE RVU of 0.61 for CCM is significantly lower than for the following similar services that cannot be billed during same period with CCM: HCPCS code G0181 (Home Healthcare Oversight) which has a combined MP and PE RVU of 1.28; HCPCS code G0182 (Hospice Care Plan Oversight) which has a combined MP and PE RVU of 1.30; CPT code 99339 (Care Plan Oversight Services) which has a combined MP and PE RVU of 0.94; and CPT code 99358 (Prolonged Services without Direct Patient Contact) which has a combined MP and PE RVU of 0.98.

Several commenters suggested that CMS's comparison with TCM, CPT code 99495, was not an appropriate comparison. One commenter asked what codes other than CPT code 99495 CMS considered as similar to CCM for purposes of CCM valuation. This commenter believed the time and intensity required for the non-face-to-face portion of CPT code 99495 is not the same as for CCM services.

Several commenters suggested that CMS should develop PE RVUs for the service using alternative methodologies than for other PFS services. For example, several commenters stated that CMS should adjust the PE RVUs to account for major infrastructure and other costs required for CCM, especially health information technology, computer equipment, 24/7 beneficiary access, extensive documentation, nursing staff and other overhead costs. One commenter believed the proposed

RVUs accounted for personnel costs but not the practice expense for health information technology, workforce retooling, and analytics.

We received many public comments on the appropriate work time and direct PE inputs for clinical staff time. Most suggested that the proposed inputs for time were too low and recommended using the RUC-recommended values (work time of 30 minutes and 60 minutes of clinical labor time). Regarding clinical labor time, some commenters believed the proposed 20 minutes of clinical labor was too low, being the 25th percentile for work time in the RUC survey, and they noted the significantly higher time reported in response to the RUC survey of 60 minutes of clinical labor time. Another commenter said that assuming 20 minutes of service time per month as typical significantly undervalues the service and questioned how CMS arrived at that number. Regarding the work time, several commenters addressed the work RVU, recommending that the proposed RVU be adjusted upwards but did not specify by how much. Several commenters noted that the RUC recommendation of 1.0 work RVU for CPT codes 99490 and 99487 (Cmplx chron care w/o pt visit) is based on median survey work times of 30 minutes and 26 minutes, respectively, for these CCM codes. (The long descriptor for CPT code 99487 is, Complex chronic care management services, with the following required elements:

- Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient;
- Chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline;
- Establishment or substantial revision of a comprehensive care plan;
- Moderate or high complexity medical decision making;
- 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month).

However several commenters did not object to the proposed valuation for GXXX1 and recommended that CMS monitor payment adequacy and appropriate valuation once the code is implemented.

Response: After consideration of the various comments on the work RVUs, we continue to believe that the most appropriate mechanism for determining the appropriate work RVU for this service is by using the non-face-to-face portion of the lower level TCM code, CPT code 99495. We continue to believe

that the work and intensity for CCM services furnished to the eligible beneficiaries is comparable to the work and intensity involved in furnishing the non-face-to-face portion of the service described by CPT code 99495. Therefore, we believe that using CPT code 99495 as the comparison code assures appropriate relativity with other similar services. The services suggested by the commenters as comparable to the CCM code require significantly more time. CPT code 99358 is for an hour of non-face-to-face time and has a work time of 60 minutes. CPT code 99339 has a work time of 40 minutes and is furnished to a significantly different patient population (those in a domiciliary or rest home). HCPCS codes G0181 and G0182 have work time of almost 60 minutes and also are furnished to significantly different patient populations.

We appreciate commenters' concerns regarding the various kinds of practice expense and malpractice liability costs that practices incur as they manage beneficiaries requiring CCM services. However, we continue to believe that our established PE and MP methodology used to value the wide ranges of services across the PFS assures that we have the appropriate relativity in our payments.

Although many commenters recommended that we use the time from the RUC survey of 60 minutes of clinical labor and 30 minutes of work time, we believe that since CCM is a new separately billable service, the survey data may be less reliable as the practitioners would have no experience with the code. Since at least 20 minutes of services are required to be furnished in order to report the service and our information, including comments, suggests that many beneficiaries who meet Medicare's criteria for CCM services would not need more than the minimum required minutes of service, we believe 60 minutes would overestimate the typical number of clinical labor minutes during one month for the typical eligible beneficiary. Accordingly, we are finalizing our proposed work and clinical labor times.

Comment: A number of commenters recommended that coinsurance should not apply to CCM services. These commenters were concerned that the \$8 estimated coinsurance amount in the proposed rule would hinder beneficiary access. Several commenters believed that CCM is a preventive service that should be exempt from beneficiary cost sharing. They noted that cost-sharing will make it challenging to reach the 20 minutes required for billing, because

beneficiaries will delay care until face-to-face is necessary.

Response: CCM services do not fall into any of the statutory preventive services benefit categories of the Act. The Secretary has the authority to add "additional preventive services" that, among other things, have been assigned an "A" or "B" rating by the United States Preventive Services Task Force, but CCM has not earned such a rating. Since CCM does not meet the criteria, we cannot designate it as an additional preventive service under section 1861(s)(2)(BB) of the Act. Further, we do not have other statutory authority that would allow us to waive the applicable coinsurance for CCM services. As discussed in the CY 2014 PFS final rule with comment period (78 FR 74424), in order to assure that beneficiaries are aware of the coinsurance for this non-face-to-face service, we are requiring that providers explain to beneficiaries the cost-sharing obligation involved in receiving CCM services and obtain their consent prior to furnishing the service. Practitioners should explain that a likely benefit of agreeing to receive CCM services is that although cost-sharing applies to these services, CCM services may help them avoid the need for more costly face to face services that entail greater cost-sharing.

Comment: Most of the commenters were concerned that the proposed payment would not be adequate for beneficiaries with complex needs who would benefit the most from CCM services. Most of the commenters recommended that we adopt more than one code to provide differential payment for more and less complex beneficiaries, using CPT CCM codes, G-code(s) or some combination thereof. Many commenters distinguished between beneficiaries that require significantly different clinical resources—those needing "complex chronic care management" and those needing only "standard chronic care or disease management." Some commenters asserted that there is a disconnect between the code descriptor for GXXX1 and the Medicare CCM scope of service, such that ambiguity in the descriptor will result in use of GXXX1 to treat a very broad spectrum of beneficiaries inconsistent with the scope of service that the commenters believed was consistent with beneficiaries with more complex needs. They believed the proposed payment amount is appropriate for beneficiaries on needing only standard chronic care management, but would significantly underpay for beneficiaries requiring complex chronic care management.

Many commenters recommended that CMS adopt the three CPT codes describing chronic care management. In addition to the CPT code that is similar to the G-code described above (CPT code 99490), there are two additional complex chronic care coordination codes (a base code and an add-on code). Since CY 2013 when the complex chronic care coordination codes became available, CMS has bundled these codes. The base code is CPT code 99487 (Cmplx chron care w/o pt visit), and the add-on is CPT code 99489 (Complex chronic care coordination services; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (list separately in addition to code for primary procedure)).

Other commenters recommended using two codes to describe CCM for different patient populations, or a base code and an add-on code to describe CCM for a single patient population. Some commenters recommended adoption of GXXX1 or CPT code 99490, plus CPT code 99487 along with the RUC-recommended values, to describe CCM for the two distinct populations that require different services. These commenters stated that there is no "typical" patient that characterizes both groups of patients, and that a large number of eligible beneficiaries (those having 2 or more chronic conditions) have serious mental health and/or substance abuse disorders and would benefit greatly from CCM services). Other commenters recommended using two G-codes, one being an add-on code for each additional 20 minutes or other time spent caring for a beneficiary with more complex needs. One commenter urged CMS to adopt an add-on code for time increments over 60 minutes. Several commenters recommended a cap on additional minutes, particularly if CMS finalizes an applicable beneficiary coinsurance for CCM services. One commenter recommended that we finalize the proposed valuation for GXXX1, also recognize CPT code 99490 (Chron care mgmt srvc 20 min) with a higher payment amount, and then collect data on the impacts of differential payment amounts.

Other commenters recommended that CMS adopt CPT code 99487 (Cmplx chron care w/o pt visit) with the scope of services for GXXX1. One commenter recommended that CMS redefine its requirements and the scope of services for GXXX1 to be more consistent with chronic disease management, using CPT code 99487. The commenter believed we should adopt CPT code 99487 with the RUC-recommended valuation. One commenter more generally

recommended that CMS adopt a higher intensity code for patients requiring 45–60 minutes or more of clinical staff time for assessment, medication management, care planning, coordination, education and advocacy.

Response: At this time, we believe that Medicare beneficiaries with two or more chronic conditions as defined under the CCM code can benefit from care management and want to make this service available to all such beneficiaries. Like all services, we recognize that some beneficiaries will need more services and some less, and thus we pay based upon the typical service. However all scope of service elements apply for delivery of CCM services to any eligible Medicare beneficiary. We will evaluate the utilization of this service to evaluate what types of beneficiaries receive the service described by this CPT code, what types of practitioners are reporting it, and consider any changes in payment that may be warranted in the coming years. We are maintaining the status indicator “B” (Bundled) for CY 2015 for the complex care coordination codes, CPT codes 99487 and 99489.

Comment: Several commenters requested that CMS create codes specific to remote patient biometric monitoring (recording vital signs and other physiological data and transmitting real-time data to physicians). Several commenters requested codes specific to or inclusive of certain hematology, nephrology, endocrine and allergy/immunology conditions, such as chronic kidney disease, end-stage renal disease, diabetes and severe asthma. One commenter recommended that CMS delay implementation of this service for CY 2015 and propose for CY 2016 specific complex chronic care codes for each of the major chronic diseases, especially diabetes.

Response: We are not convinced that the care management services are sufficiently unique based upon the beneficiary’s specific chronic conditions to warrant separate codes, especially given the beneficiary must have at least two chronic conditions. As noted above, we will be monitoring this service and will consider making changes if they appear warranted.

After consideration of the comments received on this proposal, we are finalizing the proposal with the following modification. Rather than creating a G-code we are adopting the new CPT code, 99490, to describe CCM services effective January 1, 2015. We intend to evaluate this service closely to assess whether the service is targeted to the right population and whether the

payment is appropriate for the services being furnished. As part of our evaluation, we will consider the whether this new service meets the care coordination needs of Medicare beneficiaries and if not how best to address the unmet needs.

2. CCM and TCM Services Furnished Incident to a Physician’s Service Under General Physician Supervision

In the CY 2014 PFS final rule with comment period (78 FR 74425 through 74427), we discussed how the policies relating to services furnished incident to a practitioner’s professional services apply to CCM services. (In this discussion, the term practitioner means both physicians and NPPs who are permitted to bill for services furnished incident to their own professional services.) Specifically, we addressed the policy for counting clinical staff time for services furnished incident to the billing practitioner’s services toward the minimum amount of service time required to bill for CCM services.

We established an exception to the usual rules that apply to services furnished incident to the services of a billing practitioner. Generally, under the “incident to” rules, practitioners may bill for services furnished incident to their own services if the services meet the requirements specified in our regulations at § 410.26. One of these requirements is that the “incident to” services must be furnished under direct supervision, which means that the supervising practitioner must be present in the office suite and be immediately available to provide assistance and direction throughout the service (but does not mean that the supervising practitioner must be present in the room where the service is furnished). We noted in last year’s PFS final rule with comment period that, because one of the required elements of the CCM service is beneficiary access to the practice 24-hours-a-day, 7-days-a-week, to address the beneficiary’s chronic care needs (78 FR 74426), we expect the beneficiary to be provided with a means to make timely contact with health care providers in the practice whenever necessary to address chronic care needs regardless of the time of day or day of the week. In those cases when the need for contact arises outside normal business hours, it is likely that the beneficiary’s initial contact would be with clinical staff employed by the practice (for example, a nurse) and not necessarily with a practitioner. Under these circumstances, it would be unlikely that a practitioner would be available to provide direct supervision of the service.

Therefore, in the CY 2014 PFS final rule with comment period, we created an exception to the generally applicable requirement that “incident to” services must be furnished under direct supervision. Specifically, we finalized a policy to require only general, rather than direct, supervision when CCM services are furnished incident to a practitioner’s services outside of the practice’s normal business hours by clinical staff who are direct employees of the practitioner or practice. We explained that, given the potential risk to beneficiaries that the exception to direct supervision could create, we believed that it was appropriate to design the exception as narrowly as possible (78 FR 74426). The direct employment requirement was intended to balance the less stringent general supervision requirement by ensuring that there is a direct oversight relationship between the supervising practitioner and the clinical staff personnel who provide after-hours services.

In the CY 2015 PFS proposed rule, we proposed to revise the policy that we adopted in the CY 2014 PFS final rule with comment period. We also proposed to amend our regulations to codify the requirements for CCM and TCM services furnished incident to a practitioner’s services. Specifically, we proposed to remove the requirement that, in order to count the time spent by clinical staff providing aspects of CCM services toward the CCM time requirement, the clinical staff person must be a direct employee of the practitioner or the practitioner’s practice. (We note that the existing requirement that these services be provided by clinical staff, specifically, rather than by other auxiliary personnel is an element of the service for both CCM and TCM services, rather than a requirement imposed by the “incident to” rules themselves.) We also proposed to remove the restriction that services provided by clinical staff under general (rather than direct) supervision may be counted only if they are provided outside of the practice’s normal business hours. Under our proposed revised policy, then, the time spent by clinical staff providing aspects of CCM services can be counted toward the CCM time requirement at any time, provided that the clinical staff are under the general supervision of a practitioner and all other requirements of the “incident to” regulations at § 410.26 are met.

We proposed to revise these aspects of the policy for several reasons. First, one of the required elements of the CCM service is the availability of a means for the beneficiary to make contact with

health care practitioners in the practice to address a beneficiary's urgent chronic care needs (78 FR 74418 through 74419). Other elements within the scope of CCM services are similarly required to be furnished by practitioners or clinical staff. We believe that these elements of the CCM scope of service require the presence of an organizational infrastructure sufficient to adequately support CCM services, irrespective of the nature of the employment or contractual relationship between the clinical staff and the practitioner or practice. We also believe that the elements of the CCM scope of service, such as the requirement of a care plan, ensure a close relationship between a practitioner furnishing ongoing care for a beneficiary and clinical staff providing aspects of CCM services under general supervision; and that this close working relationship is sufficient to render a requirement of a direct employment relationship or direct supervision unnecessary. Under our proposal, CCM services could be furnished "incident to" if the services are provided by clinical staff under general supervision of a practitioner whether or not they are direct employees of the practitioner or practice that is billing for the service; but the clinical staff must meet the other requirements for auxiliary personnel including those at § 410.26(a)(1). Other than the exception to permit general supervision for clinical staff, the same requirements apply to CCM services furnished incident to a practitioner's professional services as apply to other "incident to" services. Furthermore, since last year's final rule, we have had many consultations with physicians and others about the organizational structures and other factors that contribute to effective provision of CCM services. These consultations have convinced us that, for purposes of clinical staff providing aspects of CCM services, it does not matter whether the practitioner is directly available to supervise because the nature of the services are such that they can be, and frequently are, provided outside of normal business hours or while the physician is away from the office during normal business hours. This is because, unlike most other services to which the "incident to" rules apply, the CCM services are intrinsically non-face-to-face care coordination services.

In conjunction with this proposed revision to the requirements for CCM services provided by clinical staff incident to the services of a practitioner, we also proposed to adopt the same requirements for equivalent purposes in

relation to TCM services. As in the case of CCM, TCM explicitly includes separate payment for services that are not necessarily furnished face-to-face, such as coordination with other providers and follow-up with beneficiaries. It would also not be uncommon for auxiliary personnel to provide elements of the TCM services when the physician was not in the office. Generally, we believe that it is appropriate to treat separately billable care coordination services similarly whether in the form of CCM or TCM. We also believe that it would be appropriate to apply the same "incident to" rules that we are proposing for CCM services to TCM services. We did not propose to extend this policy to the required face-to-face portion of TCM. Rather, the required face-to-face portion of the service must still be furnished under direct supervision.

Therefore, we proposed to revise our regulation at § 410.26, which sets out the applicable requirements for "incident to" services, to permit TCM and CCM services provided by clinical staff incident to the services of a practitioner to be furnished under the general supervision of a physician or other practitioner. As with other "incident to" services, the physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the "incident to" service is based. We note that all other "incident to" requirements continue to apply and that the usual documentation of services provided must be included in the medical record.

Commenters uniformly supported our proposal to revise our regulation at § 410.26, which sets out the applicable requirements for "incident to" services, to permit TCM and CCM services provided by clinical staff incident to the services of a practitioner to be furnished under the general supervision of a physician or other practitioner. Under the revised regulation, then, the time spent by clinical staff providing aspects of TCM and CCM services can be counted toward the TCM or CCM time requirement at any time, provided that the clinical staff are under the general supervision of a practitioner and all requirements of the revised "incident to" regulations at § 410.26 are met.

Comment: One commenter requested guidance concerning whether (as has been the case with E/M codes) activities billed under "incident to" will not be able to also be billed under the CCM code.

Response: The purpose of our proposal was to allow elements of CCM services that are furnished by clinical

staff incident to a practitioner's professional services (under the "incident to" regulations) to be included and reported as CCM services. We are not entirely clear what the commenter is asking, but the time spent furnishing CCM services can only be counted once and for only one purpose, and each discrete service can be billed only once. Although we and our contractors provide many educational materials, practitioners who furnish Medicare covered items and services are responsible for learning how to appropriately bill each service.

Comment: One commenter urged us to revise the terminology by which we define the CCM and TCM services to reflect non-hierarchical interdisciplinary team care, rather than relying on an incident-to structure that obscures the actual provider of direct patient care. This commenter expressed concern about loss of benefits to clinicians under contract with a practice, rather than being employed by the practice. Another commenter similarly expressed concern that the expanded authorization for "general supervision" rather than "direct supervision" would provide an even greater incentive for physicians to require that any E/M service provided by an Advanced Practice Registered Nurse (APRN) in their practice be billed as "incident to" a physician's service. This could reduce transparency in billing data and diminish accountability for services for Part B beneficiaries.

Response: We do not entirely understand the basis for these concerns. We have accommodated numerous requests to include contracted employees within the scope of the "incident to" rules for purposes of counting time toward the TCM and CCM requirements. We have not otherwise proposed to revise the "incident to" and other regulations within which practitioners operate as they make decisions about whether to contract or directly employ clinical staff, or about how to bill for services provided. Although they are important within the context of the new TCM and CCM services, we believe that the revisions to our "incident to" regulation that are adopted in this final rule, are peripheral in the context of the overall employment and billing practices of physicians and group practices.

After consideration of the comments, we are finalizing our proposal to revise our regulation at § 410.26, which sets out the applicable requirements for "incident to" services, to permit the CCM and non-face-to-face portion of the TCM services provided by clinical staff incident to the services of a practitioner

to be furnished under the general supervision of a physician or other practitioner.

3. Scope of Services and Standards for CCM Services

In the CY 2014 final rule with comment period (78 FR 74414 through 74428), we defined the elements of the scope of service for CCM that are required for a practitioner to bill Medicare for the CCM service. In addition, we indicated that we intended to develop standards for practices that furnish CCM services to ensure that the practitioners who bill for these services have the capability to fully furnish them (78 FR 74415, 74418). At that time, we anticipated that we would propose these standards in the CY 2015 PFS proposed rule. We actively sought input toward development of these standards by soliciting public comments on the CY 2014 PFS final rule with comment period, through outreach to stakeholders in meetings, by convening a Technical Expert Panel, and by collaborating with federal partners such as the Office of the Assistant Secretary for Planning and Evaluation, the Office of the Assistant Secretary for Health, the Office of the National Coordinator for Health Information Technology (ONC), and the Health Resources and Services Administration. Our goal is to recognize the trend toward practice transformation and overall improved quality of care, while preventing unwanted and unnecessary care.

As we worked to develop appropriate practice standards that would meet this goal, we consistently found that many of the standards we thought were important overlapped in significant ways with the scope of service or with the billing requirements for the CCM services that had been finalized in the CY 2014 final rule with comment period. In cases where the standards we identified were not unique to CCM requirements, we found that the standards overlapped with other Medicare requirements or other federal requirements that apply generally to health care practitioners. Based upon the feedback we received, we sought to avoid duplicating other requirements or, worse, imposing conflicting requirements on practitioners that would furnish CCM services. Given the standards and requirements that are already in place for health care practitioners and applicable to those who furnish and bill for CCM services, we decided not to propose an additional set of standards that would have to be met in order for practitioners to furnish and bill for CCM services. Instead of proposing a new set of standards

applicable to only CCM services, we decided to emphasize that certain requirements are inherent in the elements of the existing scope of service for CCM services, and clarify that these must be met in order to bill for CCM services. The CCM scope of service elements finalized in the CY 2014 PFS final rule (78 FR 74414 through 74428) are as follows.

- The provision of 24-hour-a-day, 7-day-a-week access to address the patient's acute chronic care needs. To accomplish this, the patient must be provided with a means to make timely contact with health care providers in the practice to address the patient's urgent chronic care needs regardless of the time of day or day of the week.

- Continuity of care with a designated practitioner or member of the care team with whom the patient is able to get successive routine appointments.

- Care management for chronic conditions including systematic assessment of the patient's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of patient self-management of medications.

- In consultation with the patient, any caregiver and other key practitioners treating the patient, the practitioner furnishing CCM services must create a patient-centered care plan document to assure that care is provided in a way that is congruent with patient choices and values. The care plan is based on a physical, mental, cognitive, psychosocial, functional and environmental (re)assessment and an inventory of resources and supports. It is a comprehensive plan of care for all health issues, and typically includes, but is not limited to, the following elements: problem list, expected outcome and prognosis, measurable treatment goals, symptom management, planned interventions, medication management, community/social services ordered, how the services of agencies and specialists unconnected to the billing practice will be directed/coordinated, identify the individuals responsible for each intervention, requirements for periodic review and, when applicable, revision of the care plan. A full list of problems, medications and medication allergies in the EHR must inform the care plan, care coordination and ongoing clinical care.

- Management of care transitions within health care, including referrals to other clinicians, follow-up after the patient's visit to an emergency

department, and follow-up after discharges from hospitals, skilled nursing facilities, or other health care facilities. The practice must facilitate communication of relevant patient information through electronic exchange of a summary care record with other health care providers regarding these transitions. The practice must also have qualified personnel who are available to deliver transitional care services to the patient in a timely way so as to reduce the need for repeat visits to emergency departments and readmissions to hospitals, skilled nursing facilities or other health care facilities.

- Coordination with home and community based clinical service providers required to support the patient's psychosocial needs and functional deficits. Communication to and from home and community based providers regarding these patient needs must be documented in the patient's medical record.

- Enhanced opportunities for the beneficiary and any relevant caregiver to communicate with the practitioner regarding the beneficiary's care through, not only telephone access, but also through the use of secure messaging, internet or other asynchronous non face-to-face consultation methods.

Similarly, we reminded stakeholders of the following additional billing requirements established in the CY 2014 final rule with comment period (in the following list, we have changed the service period from the 2015 proposed 30-day period to the final 2015 service period of one calendar month):

- Inform the beneficiary about the availability of the CCM services from the practitioner and obtain his or her written agreement to have the services provided, including the beneficiary's authorization for the electronic communication of the patient's medical information with other treating providers as part of care coordination.

- Document in the beneficiary's medical record that all elements of the CCM service were explained and offered to the beneficiary, and note the beneficiary's decision to accept or decline the service.

- Provide the beneficiary a written or electronic copy of the care plan and document in the electronic medical record that the care plan was provided to the beneficiary.

- Inform the beneficiary of the right to stop the CCM services at any time (effective at the end of a calendar month) and the effect of a revocation of the agreement to receive CCM services.

- Inform the beneficiary that only one practitioner can furnish and be paid for

these services during the calendar month service period.

In one area, electronic health records (EHRs), we were concerned that the existing elements of the CCM service could leave some gaps in assuring that beneficiaries consistently receive care management services that offer the benefits of advanced primary care as it was envisioned when this service was created. It is clear that effective care management can be accomplished only through regular monitoring of the patient's health status, needs, and services, and through frequent communication and exchange of information with the patient and among the various health care practitioners and providers treating the patient. After gathering input from stakeholders through the CY 2014 rulemaking cycle, for 2015 we proposed a new scope of service element that would require use of a certified EHR and electronic care planning to furnish CCM services. We believed that requiring those who furnish CCM services to utilize EHR technology that has been certified by a certifying body authorized by the National Coordinator for Health Information Technology was necessary to ensure that key patient information is stored, shared and reconciled among the many practitioners and providers involved in managing the patient's chronic conditions, otherwise care could not be coordinated and managed. Requiring a certified EHR would enable members of the interdisciplinary care team to have immediate access to the most updated information informing the care plan. Therefore we proposed that the billing practitioner must utilize EHR technology certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of the EHR certification criteria identified in the then-applicable version of 45 CFR part 170. We proposed that at a minimum, the practice must utilize EHR technology that meets the certification criteria adopted at 45 CFR 170.314(a)(3), 170.314(a)(4), 170.314(a)(5), 170.314(a)(6), 170.314(a)(7) and 170.314(e)(2) pertaining to the capture of demographics, problem lists, medications, and other key elements related to the ultimate creation of an electronic summary care record. These sections of the regulation comprise the certification criteria for specific core technology capabilities (structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary) for the 2014 edition. Under the proposal, practitioners furnishing

CCM services beginning in CY 2015 would be required to utilize an EHR certified to at least these 2014 edition certification criteria. Given these 2014 edition criteria, the EHR technology would be certified to capture data and ultimately produce summary records according to the HL7 Consolidated Clinical Document Architecture standard (see 45 CFR 170.205(a)(3)).

In addition, when any of the CCM scope of service elements refers to a health or medical record, we proposed to require use of an EHR certified to at least the 2014 edition certification criteria to fulfill the scope of service element in relation to the health or medical record. As finalized in the CY 2014 PFS final rule, the scope of service elements that reference a health or medical record are:

- A full list of problems, medications and medication allergies in the EHR must inform the care plan, care coordination and ongoing clinical care.
- Communication to and from home and community based providers regarding the patient's psychosocial needs and functional deficits must be documented in the patient's medical record.
- Inform the beneficiary of the availability of CCM services and obtain his or her written agreement to have the services provided, including authorization for the electronic communication of his or her medical information with other treating providers. Document in the beneficiary's medical record that all of the CCM services were explained and offered, and note the beneficiary's decision to accept or decline these services.
- Provide the beneficiary a written or electronic copy of the care plan and document in the electronic medical record that the care plan was provided to the beneficiary.

Regarding the care plan in particular, we believed that requiring practitioners furnishing CCM services to maintain and share an electronic care plan would alleviate the errors that can occur when care plans are not systematically reconciled. To ensure that practices offering CCM services meet these needs, we proposed that CCM services must be furnished with the use of an EHR or other health IT or health information exchange platform that includes an electronic care plan that is accessible to all practitioners within the practice, including being accessible to those who are furnishing care outside of normal business hours, and that is available to be shared electronically with care team members outside of the practice. This was a more limited proposal compared

to our CY 2014 proposal that we did not finalize that would have required members of the chronic care team who are involved in the after-hours care of the patient to have access to the beneficiary's full electronic medical record (78 FR 74416 through 74417).

Regarding the clinical summary, we proposed to require technology certified to the 2014 edition for the electronic creation of the clinical summary, formatted according to the standard adopted at 45 CFR 170.205(a)(3), but we did not specify that this format must be used for the exchange of beneficiary information (79 FR 40367). For instance, we did not propose that practitioners billing for CCM services must adopt certified technology related to the exchange of a summary care record such as the transmission standard related to Direct Project Transport in 45 CFR 170.314(b)(2)(ii).

We indicated that we believed our proposed new scope of service element for a certified EHR and electronic care planning would ensure that practitioners billing for CCM could fully furnish the services, allow practitioners to innovate around the systems that they use to furnish these services, and avoid overburdening small practices. We indicated that we believed that allowing flexibility as to how practitioners capture, update, and share care plan information was important at this stage given the maturity of current EHR standards and other electronic tools in use in the market today for care planning.

In addition to seeking comment on this new proposed scope of service element, we sought comment on any changes to the scope of service or billing requirements for CCM services that may be necessary to ensure that the practitioners who bill for these services have the capability to furnish them and that we can appropriately monitor billing for these services. With the addition of the electronic health information technology element that we proposed, we believed that the elements of the scope of service for CCM services, when combined with other important federal health and safety regulations, would provide sufficient assurance that practitioners billing for CCM could fully furnish the services, and that Medicare beneficiaries receiving CCM would receive appropriate services. However we expressed special interest in receiving public feedback regarding any meaningful elements of the CCM service or beneficiary protections that may be missing from the scope of service elements and billing requirements.

The following paragraphs summarize the comments we received regarding

these elements of the scope of service for CCM services and our responses.

Comment: Some commenters were disappointed that CMS did not propose an additional set of standards. The commenters expressed concern that there would not be sufficient accountability for high quality CCM services. Some commenters recommended further development of standards such as inclusion of evidence-based self-management programs offered by community organizations, quality measures that engage patients and demonstrate improved outcomes, or a best practices guide to assist the physician community with implementation. However, many commenters opposed further standards, and agreed with CMS that additional standards would largely overlap with other Medicare requirements or were already reflected in the scope of service elements.

Response: We appreciate the commenters' concerns about ensuring quality of care. We continue to believe that with the addition of the EHR element, the required scope of service elements are sufficient for ensuring high quality CCM services in 2015. We note that section III.K of this final rule with comment period addresses quality measures for physicians' services, and stakeholders may submit suggestions for quality measures related to CCM in response to this section of the regulation.

Comment: Many commenters expressed broad support for our EHR proposal. The commenters commended the strong emphasis on data sharing and requirements for a robust EHR as vital to successful care coordination and continuity of care. Several commenters did not believe the proposal would pose a significant administrative burden. One commenter noted that use of an EHR would help practitioners to document the time spent furnishing CCM services.

Although commenters supported adoption of certified EHR technology (CEHRT) generally, many were concerned that an insufficient number of physicians have adopted CEHRT with the functionalities we proposed for CCM, especially interoperability with other providers. The commenters were also concerned that physicians practicing in rural or economically depressed areas would not have the resources to implement such technology and would be disqualified from furnishing separately billable CCM services. Many believed the proposal was laudable but premature, recommending that CMS delay adoption of the 2014 EHR certification criteria for CCM services by 3 to 4 years when they

will be more widely adopted, or phase in the 2014 certification criteria over 2 years as a requirement for 2017. Several commenters recommended that we finalize our proposal but provide hardship exceptions for certain smaller or rural practices to enable them to bill separately for CCM services in the absence of an interoperable EHR in certain circumstances, provide financial incentives, or allow other flexibility around the requirements for physicians who cannot meet them at this time. One commenter supported the proposal but suggested we allow aspects of CCM services to be furnished using fax and secure messaging technology if physicians encounter challenges with interoperability. Until EHR systems are interoperable, some commenters suggested allowing practitioners to attest that all requirements for billing CCM were met using CEHRT or an alternative technology, or to attest that all members of the care team have timely access (24/7 access in "real time" or "near real time") to the most updated information regarding the care plan through either electronic or non-electronic means, with ongoing efforts to implement interoperable EHRs. The commenters stated many practices are making patient information accessible in a timely manner to the entire care team, but have not yet fully implemented an interoperable EHR with other providers. Several commenters were concerned about the ability of current EHR technologies to share information across different providers and EHR systems. Commenters requested that CMS ensure that no certified EHR contains technological or business impediments to data sharing across disparate technology platforms used by multiple providers trying to coordinate care. In addition, many commenters were concerned about access to CCM services, and recommended that CMS prioritize access over adoption of CEHRT. Several commenters stated that not all types of physicians have access to an EHR that meets the needs of their specialty.

A number of commenters stated that CCM could be (and already is) effectively provided without any EHR or a without a certified EHR, and recommended that CMS rescind the proposal or make the EHR requirement optional. These commenters disagreed with the requirement that CCM services must be furnished with use of a certified EHR, information technology (IT) platform or exchange platform that includes a care plan, with some stating that certified EHR systems have not demonstrated improvements in the

management of chronic conditions, especially complex cases, and suggested postponing the care plan and other EHR requirements until they are proven effective and adopted by most providers. Others stated that an EHR was necessary and that CMS should require an EHR that promotes communication among various professional on the care team, includes the patient as part of the team, and enables clinical monitoring and effective care planning. Commenters indicated that many physicians accomplish this through generating or receiving electronic discharge summaries, clinical documentation, and patient-centered plans of care, but are not using certified technologies to carry out these functions and should not be penalized.

One commenter stated that only about half of all physicians had an EHR system with advanced functionalities in 2013, many current systems were not designed with interoperability in mind and transition costs are high. The commenter believed the proposed payment amount would not sufficiently cover the cost of purchasing or upgrading an EHR system, and requiring a certified EHR would limit the number of eligible physicians without significantly adding value to CCM services. Another commenter stated that only 1,000 physicians and other eligible health professionals have achieved Stage 2 of Meaningful Use of certified EHR technology, compared with more than 300,000 physicians and eligible professionals who have achieved Stage 1.

Response: We continue to believe that it is necessary to require the use of EHR technology that has been certified under the ONC Health IT Certification Program as requisite for receiving separate payment for CCM services, to ensure that practitioners have adequate capabilities to allow members of the interdisciplinary care team to have timely access to the most updated information informing the care plan. We agree with commenters that health IT tools are most effective when there are no technological or business impediments to data sharing, or disparate technology platforms used by multiple providers trying to coordinate care, and that we should ensure common functionalities as much as possible across providers. However, we also agree with commenters who expressed concern that requiring the most recent edition of EHR certification criteria could be an impediment to the broad utilization of the CCM service. In response to comments, we are modifying our proposal regarding which

edition of certified EHR technology will be required, in order to allow more flexibility as practitioners transition to the use of certified EHR technology. Accordingly, we are modifying our proposal to specify that the CCM service must be furnished using, at a minimum, the edition(s) of certification criteria that is acceptable for purposes of the EHR Incentive Programs as of December 31st of the calendar year preceding each PFS payment year (hereinafter “CCM certified technology”) to meet the final core technology capabilities (structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary). Practitioners must also use this CCM certified technology to fulfill the CCM scope of service requirements whenever the requirements reference a health or medical record. This will ensure that requirements for CCM billing under the PFS are consistent throughout each PFS payment year and are automatically updated annually according to the certification criteria required for the EHR Incentive Programs. For CCM payment in CY 2015, this policy will allow practitioners to use EHR technology certified to either the 2011 or 2014 edition(s) of certification criteria to meet the final core capabilities for CCM and to fulfill the CCM scope of service requirements whenever the requirements reference a health or medical record. We are finalizing the separate provision we proposed for the electronic care plan scope of service element without modification as discussed below. We remind stakeholders that for all electronic sharing of beneficiary information under our final CCM policies, HIPAA standards apply in the usual manner.

Comment: Several commenters questioned the relationship between the Meaningful Use criteria and the proposed EHR scope of service element for CCM. One commenter stated that none of the requirements for EHR capability for payment of CCM services should be tied to or related to Meaningful Use, because many of the Meaningful Use requirements do not apply to CCM. Another commenter supported what they understood to be our proposal, to require billing physicians to adopt an EHR and utilize it to meet the most recent standard for Meaningful Use. However, the commenter noted (similar to the previous commenter) that the current functionalities and standards for EHR technology required for Meaningful Use are not entirely aligned with the functionalities required for CCM, for

example the commenter believed that the electronic care plan need only be shared 10 percent of the time to meet Meaningful Use measures, but that CCM would require it to be available 24/7 and to all practitioners. The commenter expressed concern that practitioners might not be able to furnish CCM as envisioned by CMS due to discrepancies with the Meaningful Use criteria, and urged CMS to adopt interoperability standards for Meaningful Use that would enable successful care coordination models. Another commenter recommended that enforcement of the proposed EHR requirement be coterminous with the enforcement of Meaningful Use Stage 2 to ensure practices have the ability to comply.

Response: Although we understand why some commenters would like for the requirements for the EHR Incentive Programs and the EHR scope of service element for CCM to be identical, we do not believe that is entirely possible because of the different nature and purpose of the respective EHR specifications. In many respects they are not comparable requirements. For example, the PFS sets payment requirements prospectively for a given calendar year, while the EHR Incentive Program may change requirements mid-year. In addition, many of the Meaningful Use measures are not relevant for the provision of CCM and we believe we should only require practitioners to adopt the certified technology that is relevant to the scope of CCM services. In their attempts to meet Meaningful Use criteria for a given year, practitioners are required to use technology certified to a specific edition(s) of certification criteria to meet the CEHRT definition, and as we discussed above we are aligning the edition required to bill CCM with the edition(s) required for Meaningful Use each year. However, it is conceivable that a practitioner could use CCM certified technology to provide and be paid for CCM in a given calendar year that will not be sufficient for achieving Meaningful Use in that same year because CCM must be furnished using at least the edition(s) of certified EHR technology required for the EHR Incentive Programs as of December 31st of the prior calendar year. Also, it is possible that a practitioner could use technology certified to an edition that qualifies for CCM payment that could also be used to achieve Meaningful Use for a given calendar year, but still not meet the objectives and associated measures of a particular stage of Meaningful Use that are required to

qualify for an EHR Incentive payment or avoid a downward adjustment to payments. As the commenters noted, the Meaningful Use measures are not all relevant to the provision of CCM services, and the practitioner may not have sufficient certified technology to support all the necessary or relevant Meaningful Use objectives and measures under the EHR Incentive Programs. Certified technology is used in different ways to meet the requirements of each program. We believe that the policy we are finalizing here aligns the CCM scope of service element to the extent appropriate with the EHR Incentive Programs to achieve maximum consistency.

Comment: Several commenters asked us to clarify the requirement for the electronic care plan in relationship to the overall requirement for a certified EHR and in relationship to the 24/7 access requirement. The commenters stated they were not sure whether these proposals were independent provisions or impacted one another. The commenters stated that if CMS intended these as independent provisions, the agency should identify objective criteria to evaluate whether a particular health IT product has adequate capabilities to meet the separate requirement for the electronic care plan. The commenters stated they were not sure whether the electronic care plan would require a certified EHR, or whether there would be an exception to use of CEHRT for the care plan. The commenters recommended flexibility in how practitioners and providers capture, develop, update and share care plan information. One commenter recommended that if practitioners must attest to use of a qualifying electronic care plan, CMS should only require a simple yes/no response to minimize billing impediments. One commenter asked us to clarify the required elements of the care plan in relation to different EHR systems.

In addition, several commenters requested that we clarify whether the care plan must be electronically accessible 24/7 to all providers treating the patient's chronic conditions, those within the billing practice, or those within the billing practice who are communicating with the patient after hours. The commenters noted that providers other than the billing practitioner may not use the same certified EHR, so it would be unreasonable to expect the same care plan and other relevant information to be accessible to all providers at all times. Other commenters believed we proposed flexibility around the certified EHR requirement in relation to the

electronic care plan, and supported this proposed flexibility.

Response: Regarding the care plan, we proposed that CCM services must be furnished with the use of an EHR or other health IT or health information exchange platform (not necessarily a certified EHR) that includes an electronic care plan that is accessible at all times to the practitioners within the practice, including those who are furnishing CCM outside of normal business hours. By practitioners “within the practice,” we mean any practitioners furnishing CCM services whose minutes count towards a given practice’s time requirement for reporting the CCM billing code.

In addition, we proposed that the electronic care plan must be available to be shared electronically with care team members outside the practice (who are not billing for CCM). We sought to convey that practitioners could satisfy these requirements related to the care plan without using the certified EHR technology. We specified that the certified EHR technology is only required to accomplish activities described in the scope of service elements that specifically mention a medical record or EHR. We said that a full list of problems, medications and medication allergies in the certified EHR (which would follow structured recording formats) must inform the care plan, not that the care plan itself must be created or transmitted among providers using certified EHR technology. We note that this was a limited proposal compared to our CY 2014 proposal that we did not finalize that would have required members of the chronic care team who are involved in the after-hours care of the patient to have access to the patient’s full electronic medical record instead of just the care plan (78 FR 74416 through 74417).

Through separate requirements for the electronic care plan and the certified EHR, our intent was to require practitioners to use some form of electronic technology tool or service in fulfilling the care plan element (other than facsimile transmission), recognizing that certified EHR technology is limited in its ability to support electronic care planning at this time, and that practitioners must have flexibility to use a wide range of tools and services beyond certified EHR technology now available in the market to support electronic care planning. We intended that all care team members furnishing CCM services that are billed by a given practice (contributing to the minimum time required for billing) must have access to the electronic care

plan at all times when furnishing CCM services. However, the electronic care plan would not have to be available at all times to other non-billing practices, recognizing that other practices may not be using compatible electronic technology or participating in a health information exchange.

We are finalizing the electronic care plan and 24/7 access elements as proposed, clarifying that to satisfy the care plan scope of service element, practitioners must electronically capture care plan information and make this information available to all care team members furnishing CCM services that are billed by a given practice (counting towards the minimum monthly service time), even when furnishing CCM outside of normal business hours. In addition, practitioners must electronically share care plan information as appropriate with other providers and practitioners who are furnishing care to the patient. We are not requiring that practitioners use a specific electronic technology to meet the requirement for 24/7 access to the care plan or its transmission, only that they use an electronic technology other than facsimile. For instance, practices may satisfy the 24/7 care plan access requirement through remote access to an EHR, web-based access to a care management application, or web-based access to a health information exchange service that captures and maintains care plan information. Likewise, we are not requiring that practitioners use a specific electronic technology to meet the requirement to share care plan information electronically with other practitioners and providers who are not billing for CCM. For instance, practitioners may meet this sharing requirement through the use of secure messaging or participation in a health information exchange with those practitioners and providers, although they may not use facsimile transmission.

While we are not requiring that practitioners use a specific electronic technology at this time (other than not allowing facsimile), we may revisit this requirement as standards-based exchange of care plan information becomes more widely available in the future. We remind stakeholders that for all electronic sharing of beneficiary information under our final CCM policies, HIPAA standards apply in the usual manner.

Comment: Several commenters asked us to clarify the relationship between the certified EHR proposal and the summary record exchange requirement. Commenters believed that CMS had cited specific regulatory provisions

around exchange in the proposed rule (identified by the commenter as a Summary Record Exchange (SRE) capability tag, referring to a designation used to identify those products on the Certified Health IT Product List maintained by ONC offering technology certified to criteria around the exchange of summary care records) and should consider alternatives. The commenters were not clear as to whether they objected to what they believed to be the proposed format or the transmission method of the summary record exchange.

Response: In the CY 2014 PFS final rule with comment period, as part of the care transitions management scope of service element, we indicated that the practice must be able to facilitate the communication of relevant patient information through electronic exchange of a summary care record with other health care providers (78 FR 74418). We did not specify a standard for the “summary care record” that providers must exchange electronically, nor did we specify a method by which providers must facilitate the communication of beneficiary information, such as use of certified EHR technology. In the CY 2015 PFS proposed rule (79 FR 40367), we proposed that the practitioner must utilize EHR technology certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of the EHR certification criteria identified in the then-applicable version of 45 CFR part 170. Under one of the specific certification criteria cited, we proposed that practitioners must use technology that meets the criterion adopted at § 170.314(e)(2), which would ensure that they produce summary records formatted according to the standard adopted at § 170.205(a)(3). However, we did not propose that this formatting standard must be used for the exchange of patient information, only that in furnishing CCM services, practitioners must format their summaries according to this standard. We did not propose that providers billing for CCM services must adopt any certified technology for the exchange of a summary care record, such as the transmission standard related to Direct Project Transport in § 170.314(b)(2)(ii). We recognized that providers are currently exchanging patient information to support transitions of care in a variety of meaningful ways beyond the methods specified with 2014 edition certified technology, with the exception of faxing which would not meet the proposed scope of service requirement. The 2014

edition sets specific requirements for transmission or exchange of the summary record that technology must meet for certification, and we expected that only some practitioners could adopt and use such technology in CY 2015. Therefore we did not constrain practitioners to the exchange functionality in the 2014 edition if they utilized an alternative electronic tool.

As discussed above, our final policy will allow practitioners billing the PFS for CCM services to use the edition(s) of certification criteria that is acceptable for the EHR Incentive Programs as of December 31st of each calendar year preceding each PFS payment year to meet the final core technology capabilities (structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary). (Also practitioners must use this CCM certified technology to fulfill the CCM scope of service requirements whenever the requirements reference a health or medical record). Under this final policy, practitioners must format their structured clinical summaries according to, at a minimum, the standard that is acceptable for the EHR Incentive Programs as of December 31st of the calendar year preceding each PFS payment year.

We are finalizing our proposal that practitioners must communicate relevant patient information through electronic exchange of a summary care record to support transitions of care, with a clarification that practitioners do not have to use any specific content exchange standard in CY 2015. We did not propose and are not finalizing a requirement to use a specific tool or service to communicate beneficiary information, as long as providers do so electronically. We note however that faxing will not fulfill this requirement for exchange of the summary care record. We did not propose to modify our view, discussed in the CY 2014 PFS final rule with comment period, that practitioners furnishing and billing for CCM services must be able to support care transitions through the electronic exchange of beneficiary information in a summary care record (78 FR 74418). While certain 2014 edition certification criteria address a content standard and transmission method for exchange of a summary record, we continue to expect that only some practitioners could adopt and use such technology. Moreover, we recognize that providers are currently exchanging patient information to support transitions of care in a variety of meaningful ways beyond the methods specified in 2014 edition certification criteria. We continue to believe that at

least for CY 2015, we should allow flexibility in the selection of the electronic tool or service that is used to transmit beneficiary information in support of care transitions, as long as practitioners electronically share beneficiary information to support transitions of care. Finally we remind stakeholders that for all electronic sharing of beneficiary information under our final CCM policies, HIPAA standards apply in the usual manner.

Comment: Several commenters expressed concern about requiring a certified EHR for billing CCM. The commenters were concerned that CMS would not allow the use of non-certified technologies that may be more innovative and effective than certified technologies. Commenters requested that we clarify whether only the certified EHR (and no other electronic tool) could be used to conduct CCM services, for example the use of enhanced communication methods other than telephone. One commenter stated that many times the practice will be using the certified EHR system to carry out such activities, and there are strong Meaningful Use incentives to employ the certified EHR for these activities. However, a practice may also have other capabilities and tools that would support elements of the CCM services. These commenters asked us to clarify whether the requirement to utilize certified EHR technology is a literal statement that only certified EHR technology may be used in furnishing the scope of service elements for CCM services.

Response: We continue to believe that health IT tools are most effective when there are no technological or business impediments to data sharing, or disparate technology platforms used by multiple practitioners trying to coordinate care. For the separately billable CCM service, we believe it is necessary to establish as part of the scope of the service a certified EHR that allows for the data capture, accessibility and sharing capabilities necessary to furnish the service. Therefore, we are finalizing our proposal to require use of CCM certified technology to meet the final core technology capabilities (structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary). In addition, whenever a scope of service element references a health or medical record, CCM certified technology must be used to fulfill that scope of service element in relation to the health or medical record. We have listed above the current scope of service elements that include a reference to a health or

medical record. If both CCM certified technology and other methods are available to the practitioner to fulfill the final core technology capabilities for CCM (structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary) or the CCM scope of service elements referencing a the health or medical record, practitioners may only use the certified capability. We remind stakeholders that for all electronic sharing of beneficiary information under our final CCM policies, HIPAA standards apply in the usual manner.

Comment: One commenter recommended that we adopt the following additional 2014 EHR certification criteria:

- Patient List Creation (45 CFR 170.314(a)(14)), which would support the required element of service for preventive services and routine appointments, and could help provide registry types of functions for the practice to use in managing patients who have agreed to participate in the chronic care management service.
- Patient-Specific Education Resources (§ 170.314(a)(15)), which would help assure the ability to provide the patient with relevant educational materials about their chronic disease conditions.
- Clinical Reconciliation (§ 170.314(b)(4)), which would serve support the medication reconciliation requirement and the requirement to review patient adherence to their medication regime.
- View/Download/Transmit to a 3rd Party (§ 170.314(e)(1)), which would enable patients to access their own electronic health record and have access to information related to their care at their own convenience.
- Secure Messaging, Ambulatory Setting Only (§ 170.314(e)(3)).

Response: Some of these 2014 certification criteria are not relevant (have no corollary) in the 2011 certification criteria, so we would not require them because practitioners are not required to use the 2014 edition in CY 2015. In addition, we are requiring that providers use certified EHR technology to fulfill a limited number of the scope of service elements (summarized in Table 33). We are requiring the certified technology only for certain foundational elements, and believe we should avoid making the EHR requirement for CCM unnecessarily complex at this time. While we agree that the other features of certified EHR products mentioned by the commenter would certainly help many practitioners fulfill the other elements of the CCM

service, practitioners may be using tools other than certified technology that are adequate for the required task(s), for example, registry tools for patient list creation, educational resources, patient portals, third party reconciliation services, and secure messaging systems.

Comment: We received many comments on the scope of service elements other than the EHR, some requesting that we implement additional standards. A few commenters said CMS should consider adding a requirement for use of community based providers through a home visit at least once every 12 months to assess the home environment and the need for community based resources, or that CMS should include home and domiciliary care, group visits and community based care. Several commenters wanted us to include “remote patient monitoring” or “patient generated health data” in the scope of services, such as daily remote monitoring of physiology and biometrics. Several commenters recommended additional tools for patient self-management education and training, or “patient activation” tools. One commenter recommended we require a patient experience survey to assess the patient’s perspective regarding the CCM services they receive. Several commenters believed we should expand the medication management and medication reconciliation element to include more comprehensive medication management and more clearly define “review of adherence” to the medication regimen.

Response: Other than the scope of service element for EHR and other electronic technology, we do not believe additional changes to the scope of service elements for CCM are warranted at this time. We are requiring certified EHR technology for certain foundational or “core” elements, including structured recording of medications and medication allergies. As finalized in the scope of service in the CY 2014 PFS final rule with comment period we are also requiring medication reconciliation with review of adherence and potential interactions, and oversight of patient self-management of medications. We believe it would be overly burdensome, especially given the broad eligible beneficiary population and final RVU inputs, to include more specific requirements related to medication management, especially when greater specificity is likely not necessary to ensure adequate care. The CCM services are by definition non-face-to-face services; therefore we are not including a requirement for home or domiciliary visits or community based care

(although there is a requirement related to coordinating home and community based care). Practitioners who engage in remote monitoring of patient physiological data of eligible beneficiaries may count the time they spend reviewing the reported data towards the monthly minimum time for billing the CCM code, but cannot include the entire time the beneficiary spends under monitoring or wearing a monitoring device. If we believe changes to the scope of service elements are warranted in the future, we will propose them through notice and comment rulemaking taking the comments we received to date into consideration.

Comment: We received many comments on the scope of service elements other than the EHR, requesting that CMS implement fewer standards. Some commenters believed that other than the “incident to” provisions, the scope of service elements are administratively burdensome and it will be difficult for physicians to adequately document that they have fulfilled the requirements. Several commenters did not believe it was necessary to require written beneficiary consent. Others asked that CMS develop model beneficiary consent forms.

Response: We understand the commenters’ concerns about adequate documentation, although this issue is not unique to CCM services. We believe the additional scope of service element for the EHR and electronic sharing of the care plan and clinical summary record will create an electronic “footprint” that will facilitate documentation, including documentation of the minimum monthly amount of time spent in providing CCM services.

Regarding beneficiary consent, we believe written beneficiary consent and its documentation in the medical record is necessary because we are requiring practices to share beneficiaries’ protected health information both within and outside of the billing practice in the course of furnishing CCM services and because beneficiaries will be required to pay coinsurance on non-face-to-face services. We do not believe the content or nature of the required consent is so complex that we should develop model formats. If we believe changes to the scope of service elements are warranted in the future, we will propose them through notice and comment rulemaking taking the comments we received to date into consideration.

In summary, we are finalizing our proposal for the CCM scope of service element for EHR technology as

proposed, with the following modification. We are including as an element of the separately billable CCM service the use of, at a minimum, technology certified to the edition(s) of certification criteria that is acceptable for the EHR Incentive Programs as of December 31st of the calendar year prior to the PFS payment year (CCM certified technology), to meet the final core EHR capabilities (structured recording of demographics, problems, medications, medication allergies and the creation of a structured clinical summary record) and to fulfill all activities within the final scope of service elements that reference a health or medical record. For CCM payment in CY 2015, this policy will allow practitioners to use EHR technology certified to either the 2011 or 2014 edition(s) of certification criteria. The final scope of service elements that refer to a health or medical record, and that must be fulfilled using the CCM certified technology, are summarized in Table 33 and include the following:

- A full list of problems, medications and medication allergies in the EHR must inform the care plan, care coordination and ongoing clinical care.
- Communication to and from home and community based providers regarding the patient’s psychosocial needs and functional deficits must be documented in the patient’s medical record.
- Inform the beneficiary of the availability of CCM services and obtain his or her written agreement to have the services provided, including authorization for the electronic communication of his or her medical information with other treating providers. Document in the beneficiary’s medical record that all of the CCM services were explained and offered, and note the beneficiary’s decision to accept or decline these services.

- Provide the beneficiary a written or electronic copy of the care plan and document in the electronic medical record that the care plan was provided to the beneficiary.

We are finalizing our proposal regarding the electronic care plan scope of service element without modification. To satisfy this element, practitioners must at least electronically capture care plan information; make this information available on a 24/7 basis to all practitioners within the practice who are furnishing CCM services whose time counts towards the time requirement for the practice to bill the CCM code; and share care plan information electronically (other than by facsimile) as appropriate with other practitioners

and providers who are furnishing care to the beneficiary. We are not requiring practitioners to use a specific electronic solution to furnish the care plan element of the CCM service, only that the method must be electronic and cannot include facsimile transmission.

Similarly, we are not requiring practitioners to use a specific tool or service to communicate clinical summaries in managing care transitions,

as long as practitioners transmit the clinical summaries electronically, with the exception of faxing which will not fulfill the requirement for exchange of a summary care record. However practitioners must format their clinical summaries according to, at a minimum, the standard that is acceptable for the EHR Incentive Programs as of December 31st of the calendar year preceding each PFS payment year.

We remind stakeholders that for all electronic sharing of beneficiary information under our final CCM policies, HIPAA standards apply in the usual manner. We summarize the final requirements for the CCM scope of service elements and billing requirements for CY 2015 and their relationship to the final EHR requirements in Table 33.

TABLE 33—SUMMARY OF FINAL CCM SCOPE OF SERVICE ELEMENTS AND BILLING REQUIREMENTS FOR CY 2015

CCM Scope of service element/billing requirement	Certified EHR or other electronic technology requirement
Structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary record. A full list of problems, medications and medication allergies in the EHR must inform the care plan, care coordination and ongoing clinical care.	Structured recording of demographics, problems, medications, medication allergies, and creation of structured clinical summary records using CCM certified technology.
Access to care management services 24/7 (providing the beneficiary with a means to make timely contact with health care providers in the practice to address his or her urgent chronic care needs regardless of the time of day or day of the week).	None.
Continuity of care with a designated practitioner or member of the care team with whom the beneficiary is able to get successive routine appointments.	None.
Care management for chronic conditions including systematic assessment of the beneficiary's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of beneficiary self-management of medications.	None.
Creation of a patient-centered care plan based on a physical, mental, cognitive, psychosocial, functional and environmental (re)assessment and an inventory of resources and supports; a comprehensive care plan for all health issues. Share the care plan as appropriate with other practitioners and providers.	Must at least electronically capture care plan information; make this information available on a 24/7 basis to all practitioners within the practice whose time counts towards the time requirement for the practice to bill the CCM code; and share care plan information electronically (other than by fax) as appropriate with other practitioners and providers.
Provide the beneficiary with a written or electronic copy of the care plan and document its provision in the electronic medical record.	Document provision of the care plan as required to the beneficiary in the EHR using CCM certified technology.
Management of care transitions between and among health care providers and settings, including referrals to other clinicians; follow-up after an emergency department visit; and follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.	<ul style="list-style-type: none"> • Format clinical summaries according to CCM certified technology. • Not required to use a specific tool or service to exchange/transmit clinical summaries, as long as they are transmitted electronically (other than by fax).
Coordination with home and community based clinical service providers	Communication to and from home and community based providers regarding the patient's psychosocial needs and functional deficits must be documented in the patient's medical record using CCM certified technology.
Enhanced opportunities for the beneficiary and any caregiver to communicate with the practitioner regarding the beneficiary's care through not only telephone access, but also through the use of secure messaging, internet or other asynchronous non face-to-face consultation methods.	None.
Beneficiary consent—Inform the beneficiary of the availability of CCM services and obtain his or her written agreement to have the services provided, including authorization for the electronic communication of his or her medical information with other treating providers. Document in the beneficiary's medical record that all of the CCM services were explained and offered, and note the beneficiary's decision to accept or decline these services.	Document the beneficiary's written consent and authorization in the EHR using CCM certified technology.
Beneficiary consent—Inform the beneficiary of the right to stop the CCM services at any time (effective at the end of the calendar month) and the effect of a revocation of the agreement on CCM services.	None.
Beneficiary consent—Inform the beneficiary that only one practitioner can furnish and be paid for these services during a calendar month.	None.

4. Payment of CCM Services in CMS Models and Demonstrations

As discussed in section II.G., several CMS models and demonstrations address payment for care management services. The Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration and the Comprehensive Primary Care (CPC) Initiative both include payments for care management services that closely overlap with the scope of service for the new chronic care management services code. In these two initiatives, primary care practices are receiving per beneficiary per month payments for care management services furnished to Medicare fee-for-service beneficiaries attributed to their practices. We proposed that practitioners participating in one of these two models may not bill Medicare for CCM services furnished to any beneficiary attributed to the practice for purposes of participating in one of these initiatives, as we believe the payment for CCM services would be a duplicative payment for substantially the same services for which payment is made through the per beneficiary per month payment. However, we proposed that these practitioners may bill Medicare for CCM services furnished to eligible beneficiaries who are not attributed to the practice for the purpose of the practice's participation as part of one of these initiatives. As the Innovation Center implements new models or demonstrations that include payments for care management services, or as changes take place that affect existing models or demonstrations, we will address potential overlaps with the CCM service and seek to implement appropriate reimbursement policies. We solicited comments on this proposal. We also solicited comments on the extent to which these services may not actually be duplicative and, if so, how our reimbursement policy could be tailored to address those situations.

We received several comments that either supported or did not oppose our proposed policy regarding the payment of CCM services in CMS models and demonstrations that also pay for care management services.

The following is a summary of the other comments we received regarding our proposals on reimbursement policies.

Comment: Two commenters requested that we reconsider our proposed policy to exclude demonstration practitioners from billing for CCM services to ensure that these practitioners are not disadvantaged relative to those practitioners who do not participate in demonstrations or models.

Response: Our proposed policy does not exclude practitioners participating in demonstrations or models from billing for CCM services. To reiterate, practitioners participating in demonstrations or models may bill Medicare for CCM services for beneficiaries who are not attributed to the practices for purposes of participating in either the MAPCP or CPC. For beneficiaries who are not attributed to the practice, no care management payment is made under the MAPCP or CPC models. If the beneficiary otherwise meets the criteria for CCM services, the practitioner may furnish and bill Medicare for CCM. However, Medicare will not pay practitioners participating in MAPCP or CPC for CCM services furnished to beneficiaries attributed to the practice for the purpose of the practice's participation in either these models. We believe we have created a pathway to enable practitioners participating in CPC or MAPCP to bill Medicare for the CCM services, as not all beneficiaries treated in a practice will be attributed to the practice.

Comment: We received two comments expressing concern for confusion that might occur regarding the interaction of CCM services and the CPC model.

Response: We acknowledge that the Innovation Center will need to engage in extensive communications efforts with practitioners participating in either CPC or MAPCP to inform them of our policies regarding billing for CCM services.

Comment: One individual commented that payment for CCM "should not be constrained" by the payment in a demonstration. The commenter also said, "The two payments are completely unrelated and are made for different purposes to very different physician practices. Also, we do not believe it is possible to know with certainty whether there is overlap between a fee-for-service chronic care management payment and a payment for care coordination in a demonstration."

Response: The proposed policy aims not to constrain practitioners voluntarily participating in Innovation Center models and demonstrations, specifically CPC and MAPCP, by allowing them to bill Medicare for CCM services furnished to beneficiaries for whom they are not receiving payments as part of these initiatives. We expect the practitioners participating in these initiatives will be eligible to bill the CCM service for some beneficiaries, as there is overlap between elements of the CCM service and the models. For example, the CPC model requires practitioners to use electronic health

records that have been certified by the National Coordinator for Health Information Technology, provide patients with 24/7 access to the practice, ensure continuity of care with a designated practitioner or care team for each patient, provide care management that includes a systematic assessment of patient needs, use patient-centered care plans, and give enhanced opportunities for patient and caregiver communications. Similarly, the MAPCP demonstration is testing the patient-centered medical home model, which focuses on care management, continuity of care, and care coordination. All practitioners, who are voluntarily participating in these initiatives, receive quarterly reports indicating which beneficiaries have been attributed to their practices. After reviewing and comparing the features of the CPC and MAPCP models with the CCM service, we continue to be convinced that there is overlap. The CCM service provides appropriate payment for care management and care coordination furnished to beneficiaries with multiple chronic conditions within the current fee-for-service Medicare program, while Innovation Center models and demonstrations test alternative payment methods that promote less reliance on a fee-for-service funding stream and support primary care delivery transformation at the practice level to identify potential future alternative approaches to payment.

In response to these comments, we will engage in extensive communications explaining to practices participating in CMMI models and demonstrations, specifically the CPC and MAPCP initiatives, the policies related to care management payments under these initiatives and the CCM service. We continue to believe the payment for CCM services would be a duplicative payment for substantially the same services included in the per beneficiary per month payment under the CPC and MAPCP models. Therefore, we are finalizing our proposed policy that CMS will not pay practitioners participating in one of these two initiatives for CCM services furnished to any beneficiary attributed by the initiative to the practice. These practitioners may bill Medicare for CCM services furnished to eligible beneficiaries who are not attributed by the initiative to the practice. As the Innovation Center implements new models or demonstrations that include payments for care management services, or as changes take place that affect existing models or demonstrations, we will address potential overlaps with the

CCM service and seek to implement appropriate payment policies.

I. Outpatient Therapy Caps for CY 2015

Section 1833(g) of the Act requires application of annual, per beneficiary, limitations on the amount of expenses that can be considered as incurred expenses for outpatient therapy services under Medicare Part B, commonly referred to as “therapy caps.” There is one therapy cap for outpatient occupational therapy (OT) services and another separate therapy cap for physical therapy (PT) and speech-language pathology (SLP) services combined.

The therapy caps apply to outpatient therapy services furnished in all settings, including the once-exempt outpatient hospital setting (effective October 1, 2012) and critical access hospitals (effective January 1, 2014).

The therapy cap amounts under section 1833(g) of the Act are updated each year based on the Medicare Economic Index (MEI). Specifically, the annual caps are calculated by updating the previous year's cap by the MEI for the upcoming calendar year and rounding to the nearest \$10.00. Increasing the CY 2014 therapy cap of \$1,920 by the CY 2015 MEI of 0.8 percent and rounding to the nearest \$10.00 results in a CY 2015 therapy cap amount of \$1,940.

An exceptions process for the therapy caps has been in effect since January 1, 2006. Originally required by section 5107 of the Deficit Reduction Act of 2005 (DRA), which amended section 1833(g)(5) of the Act, the exceptions process for the therapy caps has been extended multiple times through subsequent legislation (MIEA–TRHCA, MMSEA, MIPPA, the Affordable Care Act, MMEA, TPTCCA, MCTRCA, ATRA and PAMA). The Agency's current authority to provide an exceptions process for therapy caps expires on March 31, 2015.

After expenses incurred for the beneficiary's outpatient therapy services for the year have exceeded one or both of the therapy caps, therapy suppliers and providers use the KX modifier on claims for subsequent services to request an exception to the therapy caps. By use of the KX modifier, the therapist is attesting that the services above the therapy caps are reasonable and necessary and that there is documentation of medical necessity for the services in the beneficiary's medical record.

Under section 1833(g)(5)(C) of the Act, we are required to apply a manual medical review process to therapy claims when a beneficiary's incurred

expenses for outpatient therapy services exceed a threshold amount of \$3,700. There are two separate thresholds of \$3,700, just as there are two separate therapy caps, one for OT services and one for PT and SLP services combined, and incurred expenses are counted towards the thresholds in the same manner as the caps. The statutorily required manual medical review expires March 31, 2015, consistent with the expiration of the Agency's authority to provide an exceptions process for the therapy caps. For information on the manual medical review process, go to www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medical-Review/TherapyCap.html.

J. Definition of Colorectal Cancer Screening Tests

As discussed in the proposed rule (79 FR 40368), section 1861(pp) of the Act defines “colorectal cancer screening tests” and, under section 1861(pp)(1)(C), a “screening colonoscopy” is one of the recognized procedures. Among other things, section 1861(pp)(1)(D) of the Act authorizes the Secretary to modify the tests and procedures covered under this subsection, “with such frequency and payment limits, as the Secretary determines appropriate,” in consultation with appropriate organizations. The current definition of “colorectal cancer screening tests” at § 410.37(a)(1) includes “screening colonoscopies.” Until recently, the prevailing practice for screening colonoscopies has been moderate sedation provided intravenously by the endoscopist, without resort to separately provided anesthesia.³ Based on this prevailing practice, payment for moderate sedation has accordingly been bundled into the payment for the colorectal cancer screening tests, (for example, G0104, G0105). For these procedures, because moderate sedation is bundled into the payment, the same physician cannot also report a sedation code. An anesthesia service can be billed by a second physician.

However, a recent study in *The Journal of the American Medical Association* (JAMA) cited an increase in the percentage of colonoscopies and upper endoscopy procedures furnished using an anesthesia professional, from 13.5 percent in 2003 to 30.2 percent in 2009 within the Medicare population, with a similar increase in the commercially-insured population.⁴ A

2010 study projected that the percentage of this class of procedures involving an anesthesia professional would grow to 53.4 percent by 2015.⁵ These studies suggest that the prevailing practice for endoscopies in general and screening colonoscopies in particular is undergoing a transition, and that anesthesia separately provided by an anesthesia professional is becoming the prevalent practice. In preparation for the proposed rule, we reviewed these studies and analyzed Medicare claims data. We saw the same trend in screening colonoscopies for Medicare beneficiaries with 53 percent of the screening colonoscopies for Medicare claims submitted in 2013 had a separate anesthesia claim reported.

In light of these developments, we expressed our concern in the proposed rule that the mere reference to “screening colonoscopies” in the definition of “colorectal cancer screening tests” has become inadequate. Indeed, we were convinced that the growing prevalence of separately provided anesthesia services in conjunction with screening colonoscopies reflects a change in practice patterns. Therefore, consistent with the authority delegated by section 1861(pp)(1)(D) of the Act, we proposed to revise the definition of “colorectal cancer screening tests” to adequately reflect these new patterns. Specifically, we proposed to revise the definition of “colorectal cancer screening tests” at § 410.37(a)(1)(iii) to include anesthesia that is separately furnished in conjunction with screening colonoscopies (79 FR 40369).

We also stated that our proposal to revise the definition of “colorectal cancer screening tests” in this manner would further reduce our beneficiaries' cost-sharing obligations under Part B. Screening colonoscopies have been recommended with a grade of A by the United States Preventive Services Task Force (USPSTF) and § 410.152(l)(5) provides that Medicare Part B pays 100 percent of the Medicare payment amount established under the PFS for colorectal cancer screening tests except for barium enemas (which do not have a grade A or B recommendation from the USPSTF). This regulation is based on section 1833(a)(1) of the Act, as amended by section 4104 of the Affordable Care Act, which requires 100

Outpatient Endoscopies and Colonoscopies and Associated Spending in 2003–2009. (2012). *JAMA*, 307(11):1178–1184.

⁵ Inadomi, J. M. et al. (2010). Projected increased growth rate of anesthesia professional–delivered sedation for colonoscopy and EGD in the United States: 2009 to 2015. *Gastrointestinal Endoscopy*, 72, 580–586.

³ Faulx, A. L. et al. (2005). The changing landscape of practice patterns regarding unsedated colonoscopy and propofol use: A national web survey. *Gastrointestinal Endoscopy*, 62, 9–15.

⁴ Liu H, Waxman DA, Main R, Matke S. Utilization of Anesthesia Services during

percent Medicare payment of the fee schedule amount for those “preventive services” that are appropriate for the individual and are recommended with a grade of A or B by the USPSTF. Section 4104 of the Affordable Care Act amended section 1833(a)(1) of the Act to effectively waive any Part B coinsurance that would otherwise apply for certain recommended preventive services, including screening colonoscopies. For additional discussion of the impact of section 4104 of the Affordable Care Act, and our prior rulemaking based on this provision see the CY 2011 PFS final rule with comment period (75 FR 73412 through 73431). We also noted that under § 410.160(b)(7) colorectal cancer screening tests are not subject to the Part B annual deductible and do not count toward meeting that deductible.

In implementing the amendments made by section 4104 of the Affordable Care Act, we did not provide at that time for waiving the Part B deductible and coinsurance for covered anesthesia services separately furnished in conjunction with screening colonoscopies. At that time, we believed that our payment for the screening colonoscopy, which included payment for moderate sedation services, reflected the typical screening colonoscopy. Under the current regulations, Medicare beneficiaries who receive anesthesia from a different professional than the one furnishing the screening colonoscopy would be incurring costs for the coinsurance and deductible under Part B for those separate services. With the changes in the standard of care and shifting practice patterns toward increased use of anesthesia in conjunction with screening colonoscopy, beneficiaries who receive covered anesthesia services from a different professional than the one furnishing the colonoscopy would incur costs for any coinsurance and any unmet part of the deductible for this component of the service. However, our proposed revision to the definition of “colorectal cancer screening tests” would lead to Medicare paying 100 percent of the fee schedule amounts for screening colonoscopies, including any portion attributable to anesthesia services furnished by a separate practitioner in conjunction with such tests, under § 410.152(l)(5). Similarly, this revision would also mean that expenses incurred for a screening colonoscopy, and the anesthesia services furnished in conjunction with such tests, will not be subject to the Part B deductible and will not count toward meeting that deductible under § 410.160(b)(7). We believe the proposal

encourages more beneficiaries to obtain a screening colonoscopy, which is consistent with the intent of the statutory provision to waive Medicare cost-sharing for certain recommended preventive services, and is consistent with the authority delegated to the Secretary in section 1861(pp)(1)(D) of the Act.

In light of the changing practice patterns for screening colonoscopies, continuing to require Medicare beneficiaries to bear the deductible and coinsurance expenses for separately billed anesthesia services furnished and covered by Medicare in conjunction with screening colonoscopies could become a significant barrier to these essential preventive services. As we noted when we implemented the provisions of the Affordable Care Act waiving the Part B deductible and coinsurance for these preventive services, the goal of these provisions was to eliminate financial barriers so that beneficiaries would not be deterred from receiving them (75 FR 73412). Therefore, we proposed to exercise our authority under section 1861(pp)(1)(D) of the Act to revise the definition of colorectal cancer screening tests to encourage beneficiaries to seek these services by extending the waiver of coinsurance and deductible to anesthesia or sedation services furnished in conjunction with a screening colonoscopy.

We noted in the proposed rule (79 FR 40370) that, in implementing these proposed revisions to the regulations, it would be necessary to establish a modifier for use when billing the relevant anesthesia codes for services that are furnished in conjunction with a screening colonoscopy, and thus, qualify for the waiver of the Part B deductible and coinsurance. Therefore, we noted that we would provide appropriate and timely information on this new modifier and its proper use so that physicians will be able to bill correctly for these services when the revised regulations become effective. We also noted that the valuation of colonoscopy codes, which include moderate sedation, would be subject to the same proposed review as other codes that include moderate sedation, as discussed in section II.B.6 of this final rule with comment period.

The following is a summary of the comments received on this proposal.

Comment: The majority of commenters strongly supported finalizing our proposal to revise the definition of “colorectal cancer screening tests” at § 410.37(a)(1)(iii) to include anesthesia that is furnished in conjunction with screening

colonoscopies. However, one commenter expressed concern about the timing of the proposal, and specifically that it leaves little time for implementation in CY 2015. Therefore, the commenter recommended that the proposal should be considered for implementation in CY 2016.

Response: We appreciate the support for our proposal and are finalizing it as proposed. Specifically, we are revising the definition of “colorectal cancer screening tests” at § 410.37(a)(1)(iii) to include anesthesia that is furnished in conjunction with screening colonoscopies. We disagree with the recommendation to delay implementation until CY 2016. The proposed implementation on January 1st following the finalization of the policy in the final rule follows the usual PFS schedule for implementation of payment changes. We are not aware of a reason for deviating from the usual schedule for this policy. Therefore, we are implementing this final rule, effective January 1, 2015.

Comment: Many commenters urged us to extend our proposed revision, by identifying a way under our existing authority to redefine colorectal cancer screening to include screening colonoscopy with removal of polyp, abnormal growth, or tissue during the screening encounter. Commenters stated that there is already substantial confusion among beneficiaries about why colonoscopy with polyp removal requires payment of coinsurance, while colonoscopy without polyp removal does not. The commenters maintained that our proposal to include anesthesia that is separately furnished in conjunction with screening colonoscopies within the definition of screening colonoscopy would only cause additional confusion, unless screening colonoscopies with removal of polyp, along with any anesthesia separately furnished in conjunction with such procedures, are also included within the definition. Because our proposal rule did not seek to make changes to our policies with respect to diagnostic colonoscopies, the commenters were concerned that, beneficiaries may be liable for part B coinsurance for both diagnostic colonoscopy and any anesthesia furnished in conjunction with the colonoscopy when a polyp is removed. Commenters also stated that extending our proposal in this manner would be good public policy, because it would reduce the disincentives to this essential preventive service posed by possible liability for coinsurance if a polyp is discovered and removed during a screening colonoscopy. The commenters

also emphasized that further extending the definition in this way would remove an inconsistency between Medicare policy and the new requirements for private health plans that prohibit the imposition of cost sharing when a polyp is removed under the Affordable Care Act.

Response: We understand the commenters' concerns, however, we do not have the authority to adopt the recommended revisions by regulation.

Our authority is limited by the language of the Medicare Act. Specifically, section 1834(d)(3)(D) of the Act states that, "[i]f during the course of such a screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under this part shall not be made for the screening colonoscopy but shall be made for the procedure classified as a colonoscopy with such biopsy or removal." As a result of this statutory provision, when an anticipated screening colonoscopy ends up involving a biopsy or polyp removal, Medicare cannot pay for this procedure as a screening colonoscopy. In these circumstances, Medicare pays 80 percent of the diagnostic colonoscopy procedure and the beneficiary is responsible for paying Part B coinsurance. Under the statute, when a polyp or other growth is removed, beneficiaries are responsible for Part B coinsurance for the diagnostic colonoscopy, and similarly, any Part B coinsurance for any covered anesthesia.

Comment: Commenters stated that the proposal was not clear on how the deductible will be treated in the case of anesthesia services when a polyp or other tissue is removed during a screening colonoscopy.

Response: Section 1833(b)(1) of the Act, as amended by section 4104(c) of the Affordable Care Act, waives the Part B deductible for "colorectal screening tests regardless of the code billed for the establishment of a diagnosis as a result of the test, or the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as a screening test." We explained this provision in the CY 2011 PFS final rule with comment period (75 FR 73431). We apply this policy to any surgical service furnished on the same date as a planned colorectal cancer screening test. Our regulations at § 410.152(l)(5) already require Medicare Part B to pay 100 percent of the Medicare payment amount for colorectal cancer screening tests (excluding barium enema). The statutory waiver of deductible will apply to the anesthesia services furnished in conjunction with a

colorectal cancer screening test even when a polyp or other tissue is removed during a colonoscopy. As in the case of the physician furnishing the colonoscopy service, the anesthesia professional reporting the anesthesia in conjunction with the colonoscopy where a polyp is removed would also report the PT modifier.

Comment: Commenters urged CMS to provide guidance as to whether CPT code 00810 (Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum) would be billed with a modifier to indicate whether the procedure was screening or not.

Response: Effective January 1, 2015, beneficiary coinsurance and deductible do not apply to the following anesthesia claim lines billed when furnished in conjunction with screening colonoscopy services and billed with the appropriate modifier (33): 00810 (Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum). Anesthesia professionals who furnish a separately payable anesthesia service in conjunction with a colorectal cancer screening test should include the 33 modifier on the claim line with the anesthesia service. As noted above in situations that begin as a colorectal cancer screening test, but for which another service such as colonoscopy with polyp removal is actually furnished, the anesthesia professional should report a PT modifier on the claim line rather than the 33 modifier.

Comment: Several commenters recommended that we not only finalize the revised definition of "colorectal cancer screening tests," but also take steps to ensure that our Medicare Administrative Contractors (MACs) are not inappropriately taking actions that have the effect of nullifying some or much of the intended benefit of this policy change. Specifically, these commenters requested that we prevent the current efforts by one or more Medicare contractors to limit Medicare coverage for anesthesia services furnished during a screening colonoscopy by an anesthesia professional. Another commenter urged us to clarify that this proposed expanded definition of colorectal cancer screening to include anesthesia services should not be construed to override or preempt existing or planned coverage policies on the appropriate use of these services by MACs.

Response: This final rule with comment period establishes national policy and takes precedence over any local coverage policy that limits Medicare coverage for anesthesia

services furnished during a screening colonoscopy by an anesthesia professional.

K. Payment of Secondary Interpretation of Images

In general, Medicare makes one payment for the professional component of an imaging service for each technical component (TC) service that is furnished. Under "unusual circumstances," physicians can bill for a secondary interpretation using modifier -77, for instance, when an emergency room physician conducts an x-ray, provides an interpretation, identified a questionable finding, and subsequently requests a second interpretation from a radiologist to inform treatment decisions. In all cases, a "professional component" (PC) interpretation service should only be billed for a full interpretation and report, rather than a "review," which is paid for as part of an E/M payment.

In recent years, technological advances such as the integration of picture and archiving communications systems across health systems, growth in image sharing networks and health information exchange platforms through which providers can share images, and consumer-mediated exchange of images, have greatly increased physicians' access to existing diagnostic-quality radiology images. Accessing and utilizing these images to inform the diagnosis and record an interpretation in the medical record may allow physicians to avoid ordering duplicative tests.

We solicited comments on the appropriateness of more routine billing for secondary interpretations, although we did not propose to make any changes to the treatment of these services in 2015. We wanted to determine whether there were an expanded set of circumstances under which more routine Medicare payment for a second PC for radiology services would be appropriate, and whether such a policy would be likely to reduce the incidence of duplicative advanced imaging studies.

To achieve that goal, we solicited comments on the following: the circumstances under which physicians are currently conducting secondary interpretations and whether they are seeking payment for these interpretations; whether more routine payment for secondary interpretations should be restricted to certain high-cost advanced diagnostic imaging services; considerations for valuing secondary interpretation services; the settings in which secondary interpretations chiefly occur; and considerations for

operationalizing more routine payment of secondary interpretations in a manner that would minimize burden on providers and others.

Comment: Many commenters responded to our secondary interpretation solicitation. In addition to comments on the merits of the proposals, commenters also provided helpful information about how to implement this policy. Commenters offered diverse opinions on the time period for which an existing image would be pertinent in support of a secondary interpretation. Most commenters were in agreement that cost savings would be derived from the implementation of a secondary interpretation policy but there was no consensus as to the amount of such savings. Moreover, many commenters pointed out that they were already furnishing secondary interpretations and would appreciate adoption of a policy that would allow them to receive payment for these services.

Response: We thank all the commenters for their input. Any changes to our current policy on allowing physicians to more routinely bill for secondary interpretations of images will be addressed in future rulemaking.

L. Conditions Regarding Permissible Practice Types for Therapists in Private Practice

Section 1861(p) of the Act defines outpatient therapy services to include physical therapy (PT), occupational therapy (OT), and speech-language pathology (SLP) services furnished by qualified occupational therapists, physical therapists, and speech-language pathologists in their offices and in the homes of beneficiaries. The regulations at §§ 410.59(c), 410.60(c), and 410.62(c) set forth special provisions for services furnished by therapists in private practice, including basic qualifications necessary to qualify as a supplier of OT, PT, and SLP services, respectively. As part of these basic qualifications, the current regulatory language includes descriptions of the various practice types for therapists' private practices. Based on our review of these three sections of our regulations, we became concerned that the language is not as clear as it could be—especially with regard to the relevance of whether a practice is incorporated. The regulations appear to make distinctions between unincorporated and incorporated practices, and some practice types are listed twice. Accordingly, we proposed changes to the regulatory language to remove unnecessary distinctions and

redundancies within the regulations for OT, PT, and SLP. We noted that these changes are for clarification only, and do not reflect any change in our current policy.

To consistently specify the permissible practice types (a solo practice, partnership, or group practice; or as an employee of one of these) for suppliers of outpatient therapy services in private practice (specifically for occupational therapists, physical therapists and speech-language pathologists), we proposed to replace the regulatory text at § 410.59(c)(1)(ii)(A) through (E), § 410.60(c)(1)(ii)(A) through (E), and § 410.62(c)(1)(ii)(A) through (E) and to replace it with language listing the permissible practice types without limitations for incorporated or unincorporated.

Comment: We received comments from two therapist membership associations supporting our proposed changes to the regulations. Both commenters agree that the proposed language more consistently and accurately reflects the permissible practice types for therapists in private practice.

Another commenter representing a membership association of rehabilitation physicians told us that, rather than clarifying or simplifying the existing regulations, the proposed language is more ambiguous. The commenter urged us to clarify that our proposed language would continue to allow therapists in private practice to be employed by physician groups as specified in current provisions.

Response: We appreciate the commenters' support for our proposal. With regard to the commenter that expressed concern about the clarity of the proposed regulation text as to whether therapists in private practice can be employed by a physician group, we acknowledge that the current regulation explicitly permits that practice arrangement. However, we believe that our proposed language describing the practice arrangements of private practice therapists—a solo practice, partnership, or group practice; or as an employee of one of these—clearly continues to permit therapists to practice as an employee of a physician group, whether or not incorporated. We believe the reference in the proposed regulation to “group practice” is sufficiently broad to encompass a physician group, and thus permits therapists in private practice to practice as employees of these groups, where permissible under state law.

Therefore, we are finalizing our proposed changes to the regulations for

permissible practice types for therapists in private practice at § 410.59(c)(1)(ii)(A) through (E), § 410.60(c)(1)(ii)(A) through (E), and § 410.62(c)(1)(ii)(A) through (E).

M. Payments for Practitioners Managing Patients on Home Dialysis

In the CY 2005 PFS final rule with comment period (69 FR 66357 through 66359), we established criteria for furnishing outpatient per diem ESRD-related services in partial month scenarios. We specified that use of per diem ESRD-related services is intended to accommodate unusual circumstances when the outpatient ESRD-related services would not be paid for under the monthly capitation payment (MCP), and that use of the per diem services is limited to the circumstances listed below.

- Transient patients—Patients traveling away from home (less than full month);
- Home dialysis patients (less than full month);
- Partial month where there were one or more face-to-face visits without the comprehensive visit and either the patient was hospitalized before a complete assessment was furnished, dialysis stopped due to death, or the patient received a kidney transplant.
- Patients who have a permanent change in their MCP physician during the month.

Additionally, we provided billing guidelines for partial month scenarios in the Medicare claims processing manual, publication 100–04, chapter 8, section 140.2.1. For center-based patients, we specified that if the MCP practitioner furnishes a complete assessment of the ESRD beneficiary, the MCP practitioner should bill for the full MCP service that reflects the number of visits furnished during the month. However, we did not extend this policy to home dialysis (less than a full month) because the home dialysis MCP service did not include a specific frequency of required patient visits. In other words, unlike the ESRD MCP service for center-based patients, a visit was not required for the home dialysis MCP service as a condition of payment.

In the CY 2011 PFS final rule with comment period (75 FR 73295 through 73296), we changed our policy for the home dialysis MCP service to require the MCP practitioner to furnish at least one face-to-face patient visit per month as a condition of payment. However, we inadvertently did not modify our billing guidelines for home dialysis (less than a full month) to be consistent with partial month scenarios for center-based dialysis patients. As discussed in the CY

2015 proposed rule (79 FR 40371) stakeholders have recently brought this inconsistency to our attention. After reviewing this issue, we proposed to allow the MCP physician or practitioner to bill for the age appropriate home dialysis MCP service (as described by HCPCS codes 90963 through 90966) for the home dialysis (less than a full month) scenario if the MCP practitioner furnishes a complete monthly assessment of the ESRD beneficiary and at least one face-to-face patient visit. For example, if a home dialysis patient was hospitalized during the month and at least one face-to-face outpatient visit and complete monthly assessment was furnished, the MCP practitioner should bill for the full home dialysis MCP service. We explained that this proposed change to home dialysis (less than a full month) would provide consistency with our policy for partial month scenarios pertaining to patients dialyzing in a dialysis center. We also stated that if this proposal is adopted, we would modify the Medicare Claims Processing Manual to reflect the revised billing guidelines for home dialysis in the less than a full month scenario.

A summary of the comments on this proposal and our response is provided below.

Comment: Several stakeholders strongly supported our proposed change for practitioners managing patients on home dialysis. Specifically, the commenters stated that the proposed change in policy for the home dialysis MCP service is necessary to appropriately align practitioner payment for managing home dialysis patients with center based patients, and encouraged us to finalize the change in policy as proposed. One commenter explained that the current policy for home dialysis less than a full month requires the nephrologist to “separate out the time their home dialysis patients spend in the hospital and bill for outpatient services at a daily rate instead of the full capitated payment.” The same commenter stated that “properly aligning physician payments for managing home dialysis patients (with managing center based dialysis patients) may enable more patients to consider dialyzing at home, when appropriate.”

Response: We agree with the commenters and will finalize our proposed policy change for home dialysis. We will allow the MCP practitioner to bill for the home dialysis MCP service for the home dialysis (less than a full month) scenario if the MCP practitioner furnishes a complete monthly assessment of the ESRD

beneficiary and at least one face-to-face patient visit during the month.

N. Allowed Expenditures for Physicians' Services and the Sustainable Growth Rate

1. Medicare Sustainable Growth Rate (SGR)

The SGR is an annual growth rate that applies to physicians' services paid by Medicare. The use of the SGR is intended to control growth in aggregate Medicare expenditures for physicians' services. Payments for services are not withheld if the percentage increase in actual expenditures exceeds the SGR. Rather, the PFS update, as specified in section 1848(d)(4) of the Act, is adjusted based on a comparison of allowed expenditures (determined using the SGR) and actual expenditures. If actual expenditures exceed allowed expenditures, the update is reduced. If actual expenditures are less than allowed expenditures, the update is increased.

Section 1848(f)(2) of the Act specifies that the SGR for a year (beginning with CY 2001) is equal to the product of the following four factors:

- (1) The estimated change in fees for physicians' services;
- (2) The estimated change in the average number of Medicare fee-for-service beneficiaries;
- (3) The estimated projected growth in real Gross Domestic Product per capita; and
- (4) The estimated change in expenditures due to changes in statute or regulations.

In general, section 1848(f)(3) of the Act requires us to determine the SGRs for 3 different time periods, using the best data available as of September 1 of each year. Under section 1848(f)(3) of the Act, (beginning with the FY and CY 2000 SGRs) the SGR is estimated and subsequently revised twice based on later data. (The Act also provides for adjustments to be made to the SGRs for FY 1998 and FY 1999. See the February 28, 2003 **Federal Register** (68 FR 9567) for a discussion of these SGRs). Under section 1848(f)(3)(C)(ii) of the Act, there are no further revisions to the SGR once it has been estimated and subsequently revised in each of the 2 years following the preliminary estimate. In this final rule with comment, we are making our preliminary estimate of the CY 2015 SGR, a revision to the CY 2014 SGR, and our final revision to the CY 2013 SGR.

a. Physicians' Services

Section 1848(f)(4)(A) of the Act defines the scope of physicians' services covered by the SGR. The statute

indicates that “the term ‘physicians’ services’ includes other items and services (such as clinical diagnostic laboratory tests and radiology services), specified by the Secretary, that are commonly performed or furnished by a physician or in a physician’s office, but does not include services furnished to a Medicare+Choice plan enrollee.”

We published a definition of physicians' services for use in the SGR in the November 1, 2001 **Federal Register** (66 FR 55316). We defined physicians' services to include many of the medical and other health services listed in section 1861(s) of the Act. Since that time, the statute has been amended to add new Medicare benefits. As the statute changed, we modified the definition of physicians' services for the SGR to include the additional benefits added to the statute that meet the criteria specified in section 1848(f)(4)(A).

As discussed in the CY 2010 PFS final rule with comment period (74 FR 61961), the statute provides the Secretary with clear discretion to decide whether physician-administered drugs should be included or excluded from the definition of “physicians’ services.” Exercising this discretion, we removed physician-administered drugs from the definition of physicians' services in section 1848(f)(4)(A) of the Act for purposes of computing the SGR and the levels of allowed expenditures and actual expenditures beginning with CY 2010, and for all subsequent years. Furthermore, in order to effectuate fully the Secretary’s policy decision to remove drugs from the definition of physicians' services, we removed physician-administered drugs from the calculation of allowed and actual expenditures for all prior years.

Thus, for purposes of determining allowed expenditures, actual expenditures for all years, and SGRs beginning with CY 2010 and for all subsequent years, we specified that physicians' services include the following medical and other health services if bills for the items and services are processed and paid by Medicare carriers (and those paid through intermediaries where specified) or the equivalent services processed by the Medicare Administrative Contractors:

- Physicians' services.
- Services and supplies furnished incident to physicians' services, except for the expenditures for “drugs and biologicals which are not usually self-administered by the patient.”
- Outpatient physical therapy services and outpatient occupational therapy services,

- Services of PAs, certified registered nurse anesthetists, certified nurse midwives, clinical psychologists, clinical social workers, nurse practitioners, and certified nurse specialists.

- Screening tests for prostate cancer, colorectal cancer, and glaucoma.

- Screening mammography, screening pap smears, and screening pelvic exams.

- Diabetes outpatient self-management training (DSMT) services.

- Medical Nutrition Therapy (MNT) services.

- Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests (including outpatient diagnostic laboratory tests paid through intermediaries).

- X-ray, radium, and radioactive isotope therapy.

- Surgical dressings, splints, casts, and other devices used for the reduction of fractures and dislocations.

- Bone mass measurements.

- An initial preventive physical exam.

- Cardiovascular screening blood tests.

- Diabetes screening tests.

- Telehealth services.

- Physician work and resources to establish and document the need for a power mobility device.

- Additional preventive services.

- Pulmonary rehabilitation.

- Cardiac rehabilitation.

- Intensive cardiac rehabilitation.

- Kidney disease education (KDE)

services.

- Personalized prevention plan services

b. Preliminary Estimate of the SGR for 2015

We first estimated the CY 2015 SGR in March 2014, and we made the estimate available to the MedPAC and on our Web site. Table 34 shows the March 2014 estimate and our current estimates of the factors included in the 2015 SGR. Our March 2014 estimate of the SGR was –3.6 percent. Our current estimate of the 2015 SGR is –13.7 percent. The majority of the difference between the March estimate and our current estimate of the CY 2015 SGR is explained by adjustments to reflect intervening legislative changes that

occurred after our March estimate was prepared. Subsequent to the display of the March 2014 estimate, section 101 of the Protecting Access to Medicare Act (PAMA) of 2014 continued a 0.5 percent update to the PFS conversion factor from April 1, 2014, through December 31, 2014 (relative to the 2013 conversion factor), in place of the 24.1 percent reduction that would have occurred under the SGR system on April 1, 2014. In addition, section 101 of PAMA also provides for a 0.0 percent update for services furnished on or after January 1, 2015, through March 31, 2015. While PAMA averted the large reduction in PFS rates scheduled to occur on April 1, 2014, there will be a large reduction in PFS rates on April 1, 2015, as a result of the expiration of the temporary 0.0 percent update. The law and regulation factor of the current estimate of the SGR is now a much larger reduction than previously estimated to account for the current law reduction in PFS rates scheduled to occur on April 1, 2015. We will provide more detail on the change in each of these factors below.

TABLE 34—CY 2015 SGR CALCULATION

Statutory factors	March estimate	Current estimate
Fees	1.1 percent (1.011)	0.7 percent (1.007).
Enrollment	4.0 percent (1.040)	3.9 percent (1.039).
Real Per Capita GDP	0.8 percent (1.008)	0.7 percent (1.007).
Law and Regulation	–9.0 percent (0.910)	–18.1 percent (0.819).
Total	–3.6 percent (0.964)	–13.7 percent (0.863).

Note: Consistent with section 1848(f)(2) of the Act, the statutory factors are multiplied, not added, to produce the total (that is, $1.007 \times 1.039 \times 1.007 \times 0.819 = 0.863$). A more detailed explanation of each figure is provided in section II.N.1.e. of this final rule with comment period.

c. Revised Sustainable Growth Rate for CY 2014

Our current estimate of the CY 2014 SGR is –0.8 percent. Table 35 shows our preliminary estimate of the CY 2014 SGR, which was published in the CY 2014 PFS final rule with comment period, and our current estimate. The

majority of the difference between the preliminary estimate and our current estimate of the CY 2014 SGR is explained by adjustments to reflect intervening legislative changes that have occurred since publication of the CY 2014 PFS final rule with comment period. The PFS update reduction that

would have occurred on April 1, 2014 was averted by PAMA, which has resulted in a much higher legislative factor than our estimate of the 2014 SGR in CY 2014 PFS final rule with comment period. We will provide more detail on the change in each of these factors below.

TABLE 35—CY 2014 SGR CALCULATION

Statutory factors	Estimate from CY 2014 final rule	Current estimate
Fees	0.6 percent (1.006)	0.7 Percent (1.007).
Enrollment	2.2 percent (1.022)	0.2 Percent (1.002).
Real Per Capita GDP	0.8 percent (1.008)	0.7 Percent (1.007).
Law and Regulation	–19.6 percent (0.804)	–2.4 Percent (0.976).
Total	–16.7 percent (0.833)	–0.8 Percent (0.992).

Note: Consistent with section 1848(f)(2) of the Act, the statutory factors are multiplied, not added, to produce the total (that is, $1.007 \times 1.002 \times 1.007 \times 0.976 = 0.992$). A more detailed explanation of each figure is provided in section II.N.1.e. of this final rule with comment period.

d. Final Sustainable Growth Rate for CY 2013

The SGR for CY 2013 is 1.3 percent. Table 36 shows our preliminary

estimate of the CY 2013 SGR from the CY 2013 PFS final rule with comment period, our revised estimate from the CY 2014 PFS final rule with comment period, and the final figures determined

using the best available data as of September 1, 2014. We will provide more detail on the change in each of these factors below.

TABLE 36—CY 2013 SGR CALCULATION

Statutory factors	Estimate from CY 2013 final rule	Estimate from CY 2014 final rule	Final
Fees	0.3 percent (1.003)	0.4 percent (1.004)	0.4 Percent (1.004).
Enrollment	3.6 percent (1.036)	1.0 percent (1.010)	0.5 Percent (1.005).
Real Per Capita GDP ...	0.7 percent (1.007)	0.9 percent (1.009)	0.9 Percent (1.009).
Law and Regulation	– 23.3 percent (0.767)	– .05 percent (.995)	– 0.5 Percent (0.995).
Total	– 19.7 percent (0.803)	1.8 percent (1.018)	1.3 Percent (1.013).

Note: Consistent with section 1848(f)(2) of the Act, the statutory factors are multiplied, not added, to produce the total (that is, $1.004 \times 1.005 \times 1.009 \times 0.995 = 1.013$). A more detailed explanation of each figure is provided in section II.N.1.e. of this final rule with comment period.

e. Calculation of CYs 2015, 2014, and 2013 SGRs

(1) Detail on the CY 2015 SGR

All of the figures used to determine the CY 2015 SGR are estimates that will be revised based on subsequent data. Any differences between these estimates and the actual measurement of these figures will be included in future revisions of the SGR and allowed expenditures and incorporated into subsequent PFS updates.

(a) Factor 1—Changes in Fees for Physicians' Services (Before Applying Legislative Adjustments) for CY 2015

This factor is calculated as a weighted average of the CY 2015 changes in fees for the different types of services included in the definition of physicians' services for the SGR. Medical and other health services paid using the PFS are estimated to account for approximately 89.6 percent of total allowed charges included in the SGR in CY 2015 and are updated using the percent change in the MEI. As discussed in section A of this final rule with comment period, the percent change in the MEI for CY 2015 is 0.8 percent. Diagnostic laboratory tests are estimated to represent approximately 10.4 percent of Medicare allowed charges included in the SGR for CY 2015. Medicare payments for these tests are updated by the Consumer Price Index for Urban Areas (CPI-U), which is 2.1 percent for CY 2015. Section 1833(h)(2)(A)(iv) of the Act requires that the CPI-U update applied to clinical laboratory tests be reduced by a multi-factor productivity adjustment (MFP adjustment) and, for each of years 2011 through 2015, by 1.75 percentage points (percentage adjustment). The MFP adjustment will not apply in a year where the CPI-U is zero or a percentage decrease. Further, the application of the MFP adjustment shall not result in an adjustment to the fee schedule of less

than zero for a year. However, the application of the percentage adjustment may result in an adjustment to the fee schedule being less than zero for a year and may result in payment rates for a year being less than such payment rates for the preceding year. The applicable productivity adjustment for CY 2015 is – 0.6 percent. Adjusting the CPI-U update by the productivity adjustment results in a 1.5 percent (2.1 percent (CPI-U) minus 0.6 percent (MFP adjustment)) update for CY 2015. Additionally, the percentage reduction of 1.75 percent is applied for CYs 2011 through 2015, as discussed previously. Therefore, for CY 2015, diagnostic laboratory tests will receive an update of – 0.3 percent. Table 37 shows the weighted average of the MEI and laboratory price changes for CY 2015.

TABLE 37—WEIGHTED-AVERAGE OF THE MEI AND LABORATORY PRICE CHANGES FOR CY 2015

	Weight	Update
Physician	0.896	0.8%
Laboratory	0.104	– 0.3%
Weighted-average	1.000	0.7%

We estimate that the weighted average increase in fees for physicians' services in CY 2015 under the SGR (before applying any legislative adjustments) will be 0.7 percent.

(b) Factor 2—Percentage Change in the Average Number of Part B Enrollees from CY 2014 to CY 2015

This factor is our estimate of the percent change in the average number of fee-for-service enrollees from CY 2014 to CY 2015. Services provided to Medicare Advantage (MA) plan enrollees are outside the scope of the SGR and are excluded from this estimate. We estimate that the average

number of Medicare Part B fee-for-service enrollees will increase by 3.9 percent from CY 2014 to CY 2015. Table 38 illustrates how this figure was determined.

TABLE 38—AVERAGE NUMBER OF MEDICARE PART B FEE-FOR-SERVICE ENROLLEES FROM CY 2014 TO CY 2015 (EXCLUDING BENEFICIARIES ENROLLED IN MA PLANS)

	CY 2014	CY 2015
Overall ...	49.350 million ..	50.794 million.
Medicare Advantage (MA).	16.237 million ..	16.389 million.
Net	33.113 million ..	34.405 million.
Percent Increase.	0.2 percent	3.9 percent.

An important factor affecting fee-for-service enrollment is beneficiary enrollment in MA plans. Because it is difficult to estimate the size of the MA enrollee population before the start of a CY, at this time we do not know how actual enrollment in MA plans will compare to current estimates. For this reason, the estimate may change substantially as actual Medicare fee-for-service enrollment for CY 2015 becomes known.

(c) Factor 3—Estimated Real Gross Domestic Product Per Capita Growth in CY 2015

We estimate that the growth in real GDP per capita from CY 2014 to CY 2015 will be 0.7 percent (based on the annual growth in the 10-year moving average of real GDP per capita 2006 through 2015). Our past experience indicates that there have also been changes in estimates of real GDP per capita growth made before the year begins and the actual change in real

GDP per capita growth computed after the year is complete. Thus, it is possible that this figure will change as actual information on economic performance becomes available to us in CY 2015.

(d) Factor 4—Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Statute or Regulations in CY 2015 Compared With CY 2014

The statutory and regulatory provisions that will affect expenditures for CY 2015 relative to CY 2014 are estimated to have an impact on expenditures of –18.1 percent. This is primarily due to payment reductions for eligible professionals that are not meaningful users of health information technology, the estimated reduction in PFS rates that will occur on April 1, 2015 absent a change in law, and expiration of the work GPCI floor.

(2) Detail on the CY 2014 SGR

A more detailed discussion of our revised estimates of the four elements of the CY 2014 SGR follows.

(a) Factor 1—Changes in Fees for Physicians' Services (Before Applying Legislative Adjustments) for CY 2014

This factor was calculated as a weighted-average of the CY 2014 changes in fees that apply for the different types of services included in the definition of physicians' services for the SGR in CY 2014.

We estimate that services paid using the PFS account for approximately 91.1 percent of total allowed charges included in the SGR in CY 2014. These services were updated using the CY 2014 percent change in the MEI of 0.8 percent. We estimate that diagnostic laboratory tests represent approximately 8.9 percent of total allowed charges included in the SGR in CY 2014. For CY 2014, diagnostic laboratory tests received an update of –0.8 percent.

Table 39 shows the weighted-average of the MEI and laboratory price changes for CY 2014.

TABLE 39—WEIGHTED-AVERAGE OF THE MEI, AND LABORATORY PRICE CHANGES FOR CY 2014

	Weight	Update
Physician	0.911	0.8
Laboratory	0.089	–0.8
Weighted-average	1.000	0.7

After considering the elements described in Table 39, we estimate that the weighted-average increase in fees for physicians' services in CY 2014 under

the SGR was 0.7 percent. Our estimate of this factor in the CY 2014 PFS final rule with comment period was 0.6 percent (78 FR 74393).

(b) Factor 2—Percentage Change in the Average Number of Part B Enrollees from CY 2013 to CY 2014

We estimate that the average number of Medicare Part B fee-for-service enrollees (excluding beneficiaries enrolled in Medicare Advantage plans) increased by 0.2 percent in CY 2014. Table 40 illustrates how we determined this figure.

TABLE 40—AVERAGE NUMBER OF MEDICARE PART B FEE-FOR-SERVICE ENROLLEES FROM CY 2013 TO CY 2014 (EXCLUDING BENEFICIARIES ENROLLED IN MA PLANS)

	CY 2013	CY 2014
Overall	47.878 million	49.350 million.
Medicare Advantage (MA)	14.842 million	16.237 million.
Net	33.036 million	33.113 million.
Percent Increase	0.5 percent	0.2 percent.

Our estimate of the 0.2 percent change in the number of fee-for-service enrollees, net of Medicare Advantage enrollment for CY 2014 compared to CY 2013, is different than our estimate of an increase of 2.2 percent in the CY 2014 PFS final rule with comment period (78 FR 74393). While our current projection based on data from 8 months of CY 2014 differs from our estimate of 2.2 percent when we had no actual data, it is still possible that our final estimate of this figure will be different once we have complete information on CY 2014 fee-for-service enrollment.

(c) Factor 3—Estimated Real GDP Per Capita Growth in CY 2014

We estimate that the growth in real GDP per capita will be 0.7 percent for CY 2014 (based on the annual growth in the 10-year moving average of real GDP per capita (2005 through 2014)). Our past experience indicates that there have also been differences between our estimates of real per capita GDP growth made prior to the year's end and the actual change in this factor. Thus, it is possible that this figure will change further as complete actual information on CY 2014 economic performance becomes available to us in CY 2015.

(d) Factor 4—Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Statute or Regulations in CY 2014 Compared With CY 2013

The statutory and regulatory provisions that affected expenditures in CY 2014 relative to CY 2013 are estimated to have an impact on expenditures of –2.4 percent. This impact is due to many different legislative or regulatory provisions affecting spending in 2014 relative to 2013 including a 0.5 percent update for PFS services in 2014.

(3) Detail on the CY 2013 SGR

A more detailed discussion of our final revised estimates of the four elements of the CY 2013 SGR follows.

(a) Factor 1—Changes in Fees for Physicians' Services for CY 2013

This factor was calculated as a weighted average of the CY 2013 changes in fees that apply for the different types of services included in the definition of physicians' services for the SGR in CY 2013.

We estimate that services paid under the PFS account for approximately 90.1 percent of total allowed charges included in the SGR in CY 2013. These services were updated using the CY 2013 percent change in the MEI of 0.8 percent. We estimate that diagnostic laboratory tests represent approximately 9.9 percent of total allowed charges included in the SGR in CY 2013. For CY 2013, diagnostic laboratory tests received an update of –3.0 percent.

Table 41 shows the weighted-average of the MEI and laboratory price changes for CY 2013.

TABLE 41—WEIGHTED-AVERAGE OF THE MEI, LABORATORY, AND DRUG PRICE CHANGES FOR 2013

	Weight	Update
Physician	0.901	0.8
Laboratory	0.099	–3.0
Weighted-average	1.00	0.4

After considering the elements described in Table 41, we estimate that the weighted-average increase in fees for physicians' services in CY 2013 under the SGR (before applying any legislative adjustments) was 0.4 percent. This figure is a final one based on complete data for CY 2013.

(b) Factor 2—Percentage Change in the Average Number of Part B Enrollees From CY 2012 to CY 2013

We estimate the change in the number of fee-for-service enrollees (excluding beneficiaries enrolled in MA plans) from CY 2012 to CY 2013 was 0.5 percent. Our calculation of this factor is based on complete data from CY 2013. Table 42 illustrates the calculation of this factor.

TABLE 42—AVERAGE NUMBER OF MEDICARE PART B FEE-FOR-SERVICE ENROLLEES FROM CY 2012 TO CY 2013 (EXCLUDING BENEFICIARIES ENROLLED IN MA PLANS)

	CY 2012	CY 2013
Overall	46.468 million	47.878 million.
Medicare Advantage (MA).	13.587 million	14.842 million.
Net	32.881 million	33.036 million.
Percent Change.	0.5 percent.

(c) Factor 3—Estimated Real GDP Per Capita Growth in CY 2013

We estimate that the growth in real per capita GDP was 0.9 percent in CY 2013 (based on the annual growth in the 10-year moving average of real GDP per capita (2004 through 2013)). This figure is a final one based on complete data for CY 2013.

(d) Factor 4—Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Statute or Regulations in CY 2013 Compared With CY 2012

Our final estimate for the net impact on expenditures from the statutory and regulatory provisions that affect expenditures in CY 2013 relative to CY 2012 is –0.5 percent. This impact is due to many different legislative or regulatory provisions affecting spending in 2013 relative to 2012, including

provisions of the American Taxpayer Relief Act in 2013.

2. The Update Adjustment Factor (UAF)

Section 1848(d) of the Act provides that the PFS update is equal to the product of the MEI and the UAF. The UAF is applied to make actual and target expenditures (referred to in the statute as “allowed expenditures”) equal. As discussed previously, allowed expenditures are equal to actual expenditures in a base period updated each year by the SGR. The SGR sets the annual rate of growth in allowed expenditures and is determined by a formula specified in section 1848(f) of the Act. We note that the conversion factor for the time period from January 1, 2015 through March 31, 2015 will reflect a 0.0 percent update based on section 101 of PAMA. Beginning on April 1, 2015 through December 31, 2015, the standard calculation of the PFS CF under the SGR formula would apply.

The calculation of the UAF is not affected by sequestration. Pursuant to 2 U.S.C. 906(d)(6), “The Secretary of Health and Human Services shall not take into account any reductions in payment amounts which have been or may be effected under [sequestration], for purposes of computing any adjustments to payment rates under such title XVIII.” Therefore, allowed charges, which are unaffected by sequestration, were used to calculate physician expenditures in lieu of Medicare payments plus beneficiary cost-sharing. As a result, neither actual expenditures nor allowed expenditures were adjusted to reflect the impact of sequestration.

a. Calculation Under Current Law

Under section 1848(d)(4)(B) of the Act, the UAF for a year beginning with CY 2001 is equal to the sum of the following—

- *Prior Year Adjustment Component.* An amount determined by—

++ Computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services for the prior year (the year prior to the year for which the update is being determined) and the amount of the actual expenditures for those services for that year;

++ Dividing that difference by the amount of the actual expenditures for those services for that year; and

++ Multiplying that quotient by 0.75.

• *Cumulative Adjustment Component.* An amount determined by—

++ Computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services from April 1, 1996, through the end of the prior year and the amount of the actual expenditures for those services during that period;

++ Dividing that difference by actual expenditures for those services for the prior year as increased by the SGR for the year for which the UAF is to be determined; and

++ Multiplying that quotient by 0.33.

Section 1848(d)(4)(E) of the Act requires the Secretary to recalculate allowed expenditures consistent with section 1848(f)(3) of the Act. As discussed previously, section 1848(f)(3) specifies that the SGR (and, in turn, allowed expenditures) for the upcoming CY (CY 2015 in this case), the current CY (that is, CY 2014) and the preceding CY (that is, CY 2013) are to be determined on the basis of the best data available as of September 1 of the current year. Allowed expenditures for a year generally are estimated initially and subsequently revised twice. The second revision occurs after the CY has ended (that is, we are making the second revision to CY 2013 allowed expenditures in this final rule with comment).

Table 43 shows the historical SGRs corresponding to each period through CY 2015.

TABLE 43: Annual and Cumulative Allowed and Actual Expenditures for Physicians' Services from April 1, 1996 through the End of the Upcoming Calendar Year

Period	Annual Allowed Expenditures (\$ in billions)	Annual Actual Expenditures (\$ in billions)	Cumulative Allowed Expenditures (\$ in billions)	Cumulative Actual Expenditures (\$ in billions)	FY/CY SGR
4/1/96-3/31/97	47.0	47.0	47.0	47.0
4/1/97-3/31/98	48.5	47.2	95.6	94.3	3.2
4/1/98-3/31/99	50.6	48.1	146.2	142.4	4.2
1/1/99-3/31/99	12.7	12.5	146.2	142.4
4/1/99-12/31/99	40.5	37.2	186.7	179.6	6.9
1/1/99-12/31/99	53.2	49.7	186.7	179.6
1/1/00-12/31/00	57.1	54.4	243.7	234.0	7.3
1/1/01-12/31/01	59.7	61.5	303.4	295.5	4.5
1/1/02-12/31/02	64.6	64.8	368.0	360.3	8.3
1/1/03-12/31/03	69.3	70.4	437.3	430.7	7.3
1/1/04-12/31/04	73.9	78.5	511.2	509.1	6.6
1/1/05-12/31/05	77.0	83.8	588.2	593.0	4.2
1/1/06-12/31/06	78.2	85.1	666.4	678.1	1.5
1/1/07-12/31/07	80.9	85.1	747.2	763.1	3.5
1/1/08-12/31/08	84.5	87.3	831.8	850.4	4.5
1/1/09-12/31/09	89.9	91.1	921.7	941.5	6.4
1/1/10-12/31/10	97.9	96	1,019.6	1,037.4	8.9
1/1/11-12/31/11	102.5	99.5	1,122.2	1,136.9	4.7
1/1/12-12/31/12	107.8	101.1	1,230.0	1,238.0	5.1
1/1/13-12/31/13	109.2	102.5	1,339.1	1,340.5	1.3
1/1/14-12/31/14	108.3	103.3	1,447.4	1,443.8	-0.8
1/1/15-12/31/15	93.5	N/A	1,540.9	N/A	-13.7

Notes: (1) Allowed expenditures in the first year (April 1, 1996-March 31, 1997) are equal to actual expenditures. All subsequent figures are equal to quarterly allowed expenditure figures increased by the applicable SGR. Cumulative allowed expenditures are equal to the sum of annual allowed expenditures. We provide more detailed quarterly allowed and actual expenditure data on our website at the following address: <http://www.cms.hhs.gov/SustainableGRatesConFact/>. We expect to update the website with the most current information later this month.

(2) Allowed expenditures for the first quarter of 1999 are based on the FY 1999 SGR.

(3) Allowed expenditures for the last three quarters of 1999 are based on the FY 2000 SGR.

Consistent with section 1848(d)(4)(E) of the Act, Table 43 includes our second revision of allowed expenditures for CY 2013, a recalculation of allowed expenditures for CY 2014, and our initial estimate of allowed expenditures for CY 2015. To determine the UAF for CY 2015, the statute requires that we

use allowed and actual expenditures from April 1, 1996 through December 31, 2014 and the CY 2015 SGR. Consistent with section 1848(d)(4)(E) of the Act, we will be making revisions to the CY 2014 and CY 2015 SGRs and CY 2014 and CY 2015 allowed expenditures. Because we have

incomplete actual expenditure data for CY 2014, we are using an estimate for this period. Any difference between current estimates and final figures will be taken into account in determining the UAF for future years.

We are using figures from EE10 in the following statutory formula:

$$UAF_{15} = \frac{Target_{14} - Actual_{14}}{Actual_{14}} \times 0.75 + \frac{Target_{4/96-12/14} - Actual_{4/96-12/14}}{Actual_{14} \times SGR_{15}} \times 0.33$$

UAF_{15} = Update Adjustment Factor for CY 2015 = 3.0 percent

$Target_{14}$ = Allowed Expenditures for CY 2014 = \$108.3 billion

$Actual_{14}$ = Estimated Actual Expenditures for CY 2014 = \$103.3 billion

$Target_{4/96-12/14}$ = Allowed Expenditures from 4/1/1996 - 12/31/2014 = \$1,447.40 billion

$Actual_{4/96-12/14}$ = Estimated Actual Expenditures from 4/1/1996 - 12/31/2014 = \$1,443.80 billion

SGR_{15} = -13.7 percent (0.863)

$$\frac{\$108.3 - \$103.3}{\$103.3} \times 0.75 + \frac{\$1,447.4 - \$1,443.80}{\$103.3 \times 0.863} \times 0.33 = 4.9\%$$

Section 1848(d)(4)(D) of the Act indicates that the UAF determined under section 1848(d)(4)(B) of the Act for a year may not be less than -0.07 or greater than 0.03. Since 0.049 (4.9 percent) is greater than 0.03, the UAF for CY 2015 will be 3 percent.

Section 1848(d)(4)(A)(ii) of the Act indicates that 1.0 should be added to the UAF determined under section 1848(d)(4)(B) of the Act. Thus, adding 1.0 to 0.03 makes the UAF equal to 1.03.

3. Percentage Change in the MEI for CY 2015

The MEI is required by section 1842(b)(3) of the Act, which states that prevailing charge levels beginning after June 30, 1973, may not exceed the level from the previous year except to the extent that the Secretary finds, on the basis of appropriate economic index data, that the higher level is justified by year-to-year economic changes. The current form of the MEI was detailed in the CY 2014 PFS final rule (78 FR 74264), which revised and reclassified certain cost categories, price proxies, and expense categories.

The MEI measures the weighted-average annual price change for various

inputs needed to produce physicians' services. The MEI is a fixed-weight input price index, with an adjustment for the change in economy-wide multifactor productivity. This index, which has CY 2006 base year weights, is comprised of two broad categories: (1) Physician's own time; and (2) physician's practice expense (PE).

The physician's compensation (own time) component represents the net income portion of business receipts and primarily reflects the input of the physician's own time into the production of physicians' services in physicians' offices. This category consists of two subcomponents: (1) Wages and salaries; and (2) fringe benefits.

The physician's practice expense (PE) category represents nonphysician inputs used in the production of services in physicians' offices. This category consists of wages and salaries and fringe benefits for nonphysician staff (who cannot bill independently) and other nonlabor inputs. The physician's PE component also includes the following categories of nonlabor inputs: office expenses; medical materials and

supplies; professional liability insurance; medical equipment; medical materials and supplies; and other professional expenses.

Table 44 lists the MEI cost categories with associated weights and percent changes for price proxies for the CY 2015 update. The CY 2015 non-productivity adjusted MEI update is 1.7 percent and reflects a 1.9 percent increase in physician's own time and a 1.5 percent increase in physician's PE. Within the physician's PE, the largest increase occurred in postage, which increased 5.4 percent.

For CY 2015, the increase in the MEI is 0.8 percent, which reflects an increase in the non-productivity adjusted MEI of 1.7 percent and a productivity adjustment of 0.9 percent (which is based on the 10-year moving average of economy-wide private nonfarm business multifactor productivity). The BLS is the agency that publishes the official measure of private non-farm business MFP. Please see <http://www.bls.gov/mfp>, which is the link to the BLS historical published data on the measure of MFP.

TABLE 44—INCREASE IN THE MEDICARE ECONOMIC INDEX UPDATE FOR CY 2015 ¹

Revised cost category	2006 revised cost weight (percent) ²	CY15 update (percent)
MEI Total, productivity adjusted	100.000	0.8
Productivity: 10-year moving average of MFP ¹	⁵ N/A	0.9

TABLE 44—INCREASE IN THE MEDICARE ECONOMIC INDEX UPDATE FOR CY 2015 ¹—Continued

Revised cost category	2006 revised cost weight (percent) ²	CY15 update (percent)
MEI Total, without productivity adjustment	100.000	1.7
Physician Compensation ³	50.866	1.9
Wages and Salaries	43.641	1.9
Benefits	7.225	2.0
Practice Expense	49.134	1.5
Non-physician compensation	16.553	1.8
Non-physician wages	11.885	1.8
Non-health, non-physician wages	7.249	2.0
Professional & Related	0.800	1.9
Management	1.529	2.2
Clerical	4.720	1.9
Services	0.200	1.2
Health related, non-physician wages	4.636	1.5
Non-physician benefits	4.668	1.9
Other Practice Expense	32.581	1.4
Utilities	1.266	4.0
Miscellaneous Office Expenses	2.478	1.0
Chemicals	0.723	-1.1
Paper	0.656	3.3
Rubber & Plastics	0.598	1.0
All other products	0.500	1.7
Telephone	1.501	0.0
Postage	0.898	5.4
All Other Professional Services	8.095	1.7
Professional, Scientific, and Tech. Services	2.592	1.8
Administrative and support & waste	3.052	1.9
All Other Services	2.451	1.2
Capital	10.310	1.8
Fixed	8.957	1.9
Moveable	1.353	0.8
Professional Liability Insurance ⁴	4.295	-0.1
Medical Equipment	1.978	-0.3
Medical supplies	1.760	-0.2

¹ The forecasts are based upon the latest available Bureau of Labor Statistics data on the 10-year average of BLS private nonfarm business multifactor productivity published on July 9, 2014. (<http://www.bls.gov/news.release/prod3.nr0.htm>).

² The weights shown for the MEI components are the 2006 base-year weights, which may not sum to subtotals or totals because of rounding. The MEI is a fixed-weight, Laspeyres-type input price index whose category weights indicate the distribution of expenditures among the inputs to physicians' services for CY 2006. To determine the MEI level for a given year, the price proxy level for each component is multiplied by its 2006 weight. The sum of these products (weights multiplied by the price index levels) over all cost categories yields the composite MEI level for a given year. The annual percent change in the MEI levels is an estimate of price change over time for a fixed market basket of inputs to physicians' services.

³ The measures of Productivity, Employment Cost Indexes, as well as the various Producer and Consumer Price Indexes can be found on the Bureau of Labor Statistics Web site at <http://stats.bls.gov>.

⁴ Derived from a CMS survey of several major commercial insurers.

⁵ Productivity is factored into the MEI categories as an adjustment; therefore, no explicit weight exists for productivity in the MEI.

4. Physician and Anesthesia Fee Schedule Conversion Factors for CY 2015

The CY 2015 PFS CF for January 1, 2015 through March 31, 2015 is \$35.8013. The CY 2015 PFS CF for April 1, 2015 through December 31, 2015 is \$28.2239. The CY 2015 national average anesthesia CF for January 1, 2015 through March 31, 2015 is \$22.5550. The CY 2015 national average anesthesia CF for April 1, 2015 through December 31, 2015 is \$17.7913.

a. PFS Update and Conversion Factors (1) CY 2014 PFS Update

The formula for calculating the PFS update is set forth in section 1848(d)(4)(A) of the Act. In general, the PFS update is determined by

multiplying the CF for the previous year by the percentage increase in the MEI less productivity times the UAF, which is calculated as specified under section 1848(d)(4)(B) of the Act.

(2) CY 2015 PFS Conversion Factors

Generally, the PFS CF for a year is calculated in accordance with section 1848(d)(1)(A) of the Act by multiplying the previous year's CF by the PFS update.

We note section 101 of the Medicare Improvements and Extension Act, Division B of the Tax Relief and Health Care Act of 2006 (MIEA-TRHCA) provided a 1-year increase in the CY 2007 CF and specified that the CF for CY 2008 must be computed as if the 1-year increase had never applied.

Section 101 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) provided a 6-month increase in the CY 2008 CF, from January 1, 2008, through June 30, 2008, and specified that the CF for the remaining portion of CY 2008 and the CFs for CY 2009 and subsequent years must be computed as if the 6-month increase had never applied.

Section 131 of the MIPPA extended the increase in the CY 2008 CF that applied during the first half of the year to the entire year, provided for a 1.1 percent increase to the CY 2009 CF, and specified that the CFs for CY 2010 and subsequent years must be computed as if the increases for CYs 2007, 2008, and 2009 had never applied.

Section 1011(a) of the DODAA and section 5 of the TEA specified a zero

percent update for CY 2010, effective January 1, 2010 through March 31, 2010.

Section 4 of the Continuing Extension Act of 2010 (CEA) extended the zero percent update for CY 2010 through May 31, 2010.

Subsequently, section 101(a)(2) of the PACMBPRA provided for a 2.2 percent update to the CF, effective from June 1, 2010 to November 30, 2010.

Section 2 of the Physician Payment and Therapy Relief Act of 2010 (Pub. L. 111–286) extended the 2.2 percent update through the end of CY 2010.

Section 101 of the MMEA provided a zero percent update for CY 2011, effective January 1, 2011 through December 31, 2011, and specified that the CFs for CY 2012 and subsequent years must be computed as if the increases in previous years had never applied.

Section 301 of the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA) provided a zero percent update effective January 1, 2012 through February 29, 2012, and specified that the CFs for subsequent time periods must be computed as if the increases in previous years had never applied.

Section 3003 of the Middle Class Tax Relief and Job Creation Act of 2012 (Job Creation Act) provided a zero percent update effective March 1, 2012 through December 31, 2012, and specified that the CFs for subsequent time periods must be computed as if the increases in previous years had never applied.

Section 601 of the American Taxpayer Relief Act (ATRA) of 2012 (Pub. L. 112–240) provided a zero percent update for

CY 2013, effective January 1, 2013 through December 31, 2013, and specified that the CFs for subsequent time periods must be computed as if the increases in previous years had not been applied.

Section 1101 of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) provided a 0.5 percent update to the PFS CF, effective January 1, 2014 through March 31, 2014 and specified that the CFs for subsequent time periods must be computed as if the increases in previous years had not been applied.

Section 101 of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93) (PAMA) extended this 0.5 percent update through December 31, 2014. Section 101 of the PAMA also provides a 0.0 percent update for services furnished on or after January 1, 2015, through March 31, 2015, and specified that the CFs for subsequent time periods must be computed as if the increases in previous years had not been applied.

Therefore, under current law, the CF that would be in effect in CY 2014 had the prior increases specified above not applied is \$27.2006.

In addition, when calculating the PFS CF for a year, section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ more than \$20 million from what it would have been in the absence of these changes. If this threshold is exceeded, we must make adjustments to preserve budget neutrality. We estimate that CY 2015 RVU changes would result in an increase in Medicare physician

expenditures of more than \$20 million. Accordingly, we are decreasing the CF by 0.06 percent to offset this estimated increase in Medicare physician expenditures due to the CY 2015 RVU changes.

For January 1, 2015 through March 31, 2015, the PFS update will be 0.0 percent consistent with section 101 of PAMA. After applying the budget neutrality adjustment described above, the conversion factor for January 1, 2015 through March 31, 2015 will be \$35.8013.

After March 31, 2015 the standard calculation of the PFS CF under the SGR formula would apply. Therefore, from April 1, 2015 through December 31, 2015 the conversion factor would be \$28.2239. This final rule with comment period announces a reduction to payment rates for physicians' services of 21.2 percent during this time period in CY 2015 under the SGR formula.

By law, we are required to make these reductions in accordance with section 1848(d) and (f) of the Act, and these reductions can only be averted by an Act of Congress. While Congress has provided temporary relief from these reductions every year since 2003, a long-term solution is critical. We will continue to work with Congress to fix this untenable situation so doctors and beneficiaries no longer have to worry about the stability and adequacy of payments from Medicare under the PFS.

We illustrate the calculation of the CY 2015 PFS CF in Table 45.

TABLE 45—CALCULATION OF THE CY 2015 PFS CF

January 1, 2015 through March 31, 2015		
Conversion Factor in effect in CY 2014	\$35.8228
Update	0.0 percent (1.00)
CY 2015 RVU Budget Neutrality Adjustment	– 0.06 percent (0.9994)
CY 2015 Conversion Factor (1/1/2015 through 3/31/2015)	\$35.8013
April 1, 2015 through December 31, 2015		
Conversion Factor in effect in CY 2014	\$35.8228
CY 2014 Conversion Factor had statutory increases not applied	\$27.2006
CY 2015 Medicare Economic Index	0.8 percent (1.008)
CY 2015 Update Adjustment Factor	– 3.0 percent (1.03)
CY 2015 RVU Budget Neutrality Adjustment	– 0.06 percent (0.9994)
CY 2015 Conversion Factor (4/1/2015 through 12/31/2015)	\$28.2239
Percent Change in Conversion Factor on 4/1/2015 (relative to the CY 2014 CF)	– 21.2%
Percent Change in Update (without budget neutrality adjustment) on 4/1/2015 (relative to the CY 2014 CF)	– 20.9%

We note payment for services under the PFS will be calculated as follows:

Payment = [(Work RVU × Work GPCI) + (PE RVU × PE GPCI) + (Malpractice RVU × Malpractice GPCI)] × CF.

b. Anesthesia Conversion Factors

We calculate the anesthesia CFs as indicated in Table 46. Anesthesia services do not have RVUs like other PFS services. Therefore, we account for any necessary RVU adjustments through

an adjustment to the anesthesia CF to simulate changes to RVUs. More specifically, if there is an adjustment to the work, PE, or malpractice RVUs, these adjustments are applied to the respective shares of the anesthesia CF as

these shares are proxies for the work, PE, and malpractice RVUs for anesthesia services. Information regarding the anesthesia work, PE, and malpractice shares can be found at the following: <https://www.cms.gov/center/anesth.asp>.

The anesthesia CF in effect in CY 2014 is \$22.6765. Section 101 of PAMA provides for a 0.0 percent update from January 1, 2015 through March 31, 2015. After applying the 0.9994 budget neutrality factor described above, the anesthesia CF in effect from January 1,

2015 through March 31, 2015 will be \$22.5550.

The table below includes adjustments to the anesthesia CF that are analogous to the physician fee schedule CF with other adjustments that are specific to anesthesia. In order to calculate the CY 2015 anesthesia CF for April 1, 2015 through December 31, 2015, the statute requires us to calculate the CFs for all previous years as if the various legislative changes to the CFs for those years had not occurred. The resulting CF is then adjusted for the update (the

MEI, less multi-factor productivity and increased by the UAF). The national average CF is then adjusted for anesthesia specific work, practice expense and malpractice factors that must be applied to the anesthesia CF as the anesthesia fee schedule does not have RVUs. Accordingly, under current law, the anesthesia CF in effect in CY 2015 for the time period from April 1, 2015 through December 31, 2015 is \$17.7913. We illustrate the calculation of the CY 2015 anesthesia CFs in Table 45.

TABLE 46—CALCULATION OF THE CY 2015 ANESTHESIA CF

January 1, 2015 through March 31, 2015		
CY 2014 National Average Anesthesia CF	\$22.6765
Update	0.0 percent (1.00)	
CY 2015 RVU Budget Neutrality Adjustment	0.0006 percent (0.9994)	
CY 2015 Anesthesia Fee Schedule Practice Expense Adjustment	0.005 percent (.99524)	
CY 2015 National Average Anesthesia CF (1/1/2015 through 3/31/2015)	\$22.5550
April 1, 2015 through December 31, 2015		
2014 National Average Anesthesia Conversion Factor in effect in CY 2015	\$22.6765
2014 National Anesthesia Conversion Factor had Statutory Increases Not Applied	\$17.2283
CY 2015 Medicare Economic Index	0.8 percent (1.008)	
CY 2015 Update Adjustment Factor	3.0 percent (0.9994)	
CY 2015 Budget Neutrality Work and Malpractice Adjustment	– 0.06 percent (0.9994)	
CY 2015 Anesthesia Fee Schedule Practice Expense Adjustment	0.005 percent (.99524)	
CY 2015 Anesthesia Conversion Factor (4/1/2015 through 12/31/2015)	\$17.7913
Percent Change from 2014 to 2015 (4/1/2015 through 12/31/2015)	– 21.5%

III. Other Provisions of the Final Rule With Comment Period Regulation

A. Ambulance Extender Provisions

1. Amendment to Section 1834(l)(13) of the Act

Section 146(a) of the MIPPA amended section 1834(l)(13)(A) of the Act to specify that, effective for ground ambulance services furnished on or after July 1, 2008 and before January 1, 2010, the ambulance fee schedule amounts for ground ambulance services shall be increased as follows:

- For covered ground ambulance transports that originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 3 percent.
- For covered ground ambulance transports that do not originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 2 percent.

The payment add-ons under section 1834(l)(13)(A) of the Act have been extended several times. Recently, section 1104(a) of the Pathway for SGR Reform Act of 2013, enacted on December 26, 2013, as Division B (Medicare and Other Health Provisions)

of Pub L. 113–67, amended section 1834(l)(13)(A) of the Act to extend the payment add-ons described above through March 31, 2014. Subsequently, section 104(a) of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93, enacted on April 1, 2014) amended section 1834(l)(13)(A) of the Act to extend the payment add-ons again through March 31, 2015. Thus, these payment add-ons also apply to covered ground ambulance transports furnished before April 1, 2015. (For a discussion of past legislation extending section 1834(l)(13) of the Act, please see the CY 2014 PFS final rule (78 FR 74438 through 74439)).

These statutory requirements are self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase, and does not require any substantive exercise of discretion on the part of the Secretary. In the CY 2015 PFS proposed rule (79 FR 40372), we proposed to revise § 414.610(c)(1)(ii) to conform the regulations to these statutory requirements. We received one comment regarding this proposal. A summary of the comment we received and our response are set forth below.

Comment: One commenter supported the implementation of the ambulance

payment add-ons. The commenter also agreed that these provisions are self-implementing.

Response: We thank the commenter for their support of these provisions.

After consideration of the public comment received, we are finalizing our proposal to revise § 414.610(c)(1)(ii) to conform the regulations to these statutory requirements.

2. Amendment to Section 1834(l)(12) of the Act

Section 414(c) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173, enacted on December 8, 2003) (MMA) added section 1834(l)(12) to the Act, which specified that in the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010, for which transportation originates in a qualified rural area (as described in the statute), the Secretary shall provide for a percent increase in the base rate of the fee schedule for such transports. The statute requires this percent increase to be based on the Secretary's estimate of the average cost per trip for such services (not taking into account mileage) in the lowest quartile of all rural county populations as compared to the average cost per trip

for such services (not taking into account mileage) in the highest quartile of rural county populations. Using the methodology specified in the July 1, 2004 interim final rule (69 FR 40288), we determined that this percent increase was equal to 22.6 percent. As required by the MMA, this payment increase was applied to ground ambulance transports that originated in a “qualified rural area”; that is, to transports that originated in a rural area included in those areas comprising the lowest 25th percentile of all rural populations arrayed by population density. For this purpose, rural areas included Goldsmith areas (a type of rural census tract). This rural bonus is sometimes referred to as the “Super Rural Bonus” and the qualified rural areas (also known as “super rural” areas) are identified during the claims adjudicative process via the use of a data field included on the CMS-supplied ZIP code File.

The Super Rural Bonus under section 1834(l)(12) of the Act has been extended several times. Recently, section 1104(b) of the Pathway for SGR Reform Act of 2013, enacted on December 26, 2013, as Division B (Medicare and Other Health Provisions) of Pub. L. 113–67, amended section 1834(l)(12)(A) of the Act to extend this rural bonus through March 31, 2014. Subsequently, section 104(b) of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93, enacted on April 1, 2014) amended section 1834(l)(12)(A) of the Act to extend this rural bonus again through March 31, 2015. Therefore, we are continuing to apply the 22.6 percent rural bonus described above (in the same manner as in previous years) to ground ambulance services with dates of service before April 1, 2015 where transportation originates in a qualified rural area. (For a discussion of past legislation extending section 1834(l)(12) of the Act, please see the CY 2014 PFS final rule (78 FR 74439 through 74440)).

These statutory provisions are self-implementing. Together, these statutory provisions require a 15-month extension of this rural bonus (which was previously established by the Secretary) through March 31, 2015, and do not require any substantive exercise of discretion on the part of the Secretary. In the CY 2015 PFS proposed rule (79 FR 40372), we proposed to revise § 414.610(c)(5)(ii) to conform the regulations to these statutory requirements. We received one comment regarding this proposal. A summary of the comment we received and our response are set forth below.

Comment: One commenter supported the implementation of the percent

increase in the base rate of the fee schedule for transports in areas defined as super rural. The commenter also agreed with CMS that these provisions are self-implementing.

Response: We thank the commenter for their support of these provisions.

After consideration of the public comment received, we are finalizing our proposal to revise § 414.610(c)(5)(ii) to conform the regulations to these statutory requirements.

B. Changes in Geographic Area Delineations for Ambulance Payment

1. Background

Under the ambulance fee schedule, the Medicare program pays for ambulance transportation services for Medicare beneficiaries when other means of transportation are contraindicated by the beneficiary’s medical condition, and all other coverage requirements are met. Ambulance services are classified into different levels of ground (including water) and air ambulance services based on the medically necessary treatment provided during transport.

These services include the following levels of service:

- For Ground—
 - ++ Basic Life Support (BLS) (emergency and non-emergency)
 - ++ Advanced Life Support, Level 1 (ALS1) (emergency and non-emergency)
 - ++ Advanced Life Support, Level 2 (ALS2)
 - ++ Paramedic ALS Intercept (PI)
 - ++ Specialty Care Transport (SCT)
- For Air—
 - ++ Fixed Wing Air Ambulance (FW)
 - ++ Rotary Wing Air Ambulance (RW)

a. Statutory Coverage of Ambulance Services

Under sections 1834(l) and 1861(s)(7) of the Act, Medicare Part B (Supplemental Medical Insurance) covers and pays for ambulance services, to the extent prescribed in regulations, when the use of other methods of transportation would be contraindicated by the beneficiary’s medical condition.

The House Ways and Means Committee and Senate Finance Committee Reports that accompanied the 1965 Social Security Amendments suggest that the Congress intended that—

- The ambulance benefit cover transportation services only if other means of transportation are contraindicated by the beneficiary’s medical condition; and
- Only ambulance service to local facilities be covered unless necessary services are not available locally, in

which case, transportation to the nearest facility furnishing those services is covered (H.R. Rep. No. 213, 89th Cong., 1st Sess. 37 and Rep. No. 404, 89th Cong., 1st Sess. Pt 1, 43 (1965)).

The reports indicate that transportation may also be provided from one hospital to another, to the beneficiary’s home, or to an extended care facility.

b. Medicare Regulations for Ambulance Services

Our regulations relating to ambulance services are set forth at 42 CFR part 410, subpart B and 42 CFR part 414, subpart H. Section 410.10(i) lists ambulance services as one of the covered medical and other health services under Medicare Part B. Therefore, ambulance services are subject to basic conditions and limitations set forth at § 410.12 and to specific conditions and limitations included at § 410.40 and § 410.41. Part 414, subpart H, describes how payment is made for ambulance services covered by Medicare.

2. Provisions of the Final Rule

Historically, the Medicare ambulance fee schedule has used the same geographic area designations as the acute care hospital inpatient prospective payment system (IPPS) and other Medicare payment systems to take into account appropriate urban and rural differences. This promotes consistency across the Medicare program, and it provides for use of consistent geographic standards for Medicare payment purposes.

The current geographic areas used under the ambulance fee schedule are based on OMB standards published on December 27, 2000 (65 FR 82228 through 82238), Census 2000 data, and Census Bureau population estimates for 2007 and 2008 (OMB Bulletin No. 10–02). For a discussion of OMB’s delineation of Core-Based Statistical Areas (CBSAs) and our implementation of the CBSA definitions under the ambulance fee schedule, we refer readers to the preamble of the CY 2007 Ambulance Fee Schedule proposed rule (71 FR 30358 through 30361) and the CY 2007 PFS final rule (71 FR 69712 through 69716). On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which established revised delineations for Metropolitan Statistical Areas (MSAs), Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. A copy of this bulletin may be obtained at <http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf>. According to OMB, “[t]his

bulletin provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010, in the **Federal Register** (75 FR 37246–37252) and Census Bureau data.” OMB defines an MSA as a CBSA associated with at least one urbanized area that has a population of at least 50,000, and a Micropolitan Statistical Area (referred to in this discussion as a Micropolitan Area) as a CBSA associated with at least one urban cluster that has a population of at least 10,000 but less than 50,000 (75 FR 37252). Counties that do not qualify for inclusion in a CBSA are deemed “Outside CBSAs.” We note that, when referencing the new OMB geographic boundaries of statistical areas, we are using the term “delineations” consistent with OMB’s use of the term (75 FR 37249).

Although the revisions OMB published on February 28, 2013 are not as sweeping as the changes made when we adopted the CBSA geographic designations for CY 2007, the February 28, 2013 OMB bulletin does contain a number of significant changes. For example, we stated in the CY 2015 PFS proposed rule (79 FR 40373) that if we adopt the revised OMB delineations, there would be new CBSAs, urban counties that would become rural, rural counties that would become urban, and existing CBSAs that would be split apart. We have reviewed our findings and impacts relating to the new OMB delineations, and find no compelling reason to further delay implementation. We stated in the proposed rule that we believe it is important for the ambulance fee schedule to use the latest labor market area delineations available as soon as reasonably possible to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts.

Additionally, in the FY 2015 IPPS proposed rule (79 FR 28055), we also proposed to adopt OMB’s revised delineations to identify urban areas and rural areas for purposes of the IPPS wage index. This proposal was finalized in the FY 2015 IPPS final rule (79 FR 49952). For the reasons discussed above, we believe it would be appropriate to adopt the same geographic area delineations for use under the ambulance fee schedule as are used under the IPPS and other Medicare payment systems. Thus, we proposed to implement the new OMB delineations as described in the February 28, 2013 OMB Bulletin No. 13–01 beginning in

CY 2015 to more accurately identify urban and rural areas for ambulance fee schedule payment purposes. We believe that the updated OMB delineations more realistically reflect rural and urban populations, and that the use of such delineations under the ambulance fee schedule would result in more accurate payment. Under the ambulance fee schedule, consistent with our current definitions of urban and rural areas (§ 414.605), MSAs would continue to be recognized as urban areas, while Micropolitan and other areas outside MSAs, and rural census tracts within MSAs (as discussed below), would be recognized as rural areas.

In addition to the OMB’s statistical area delineations, the current geographic areas used in the ambulance fee schedule also are based on rural census tracts determined under the most recent version of the Goldsmith Modification. These rural census tracts are considered rural areas under the ambulance fee schedule (see § 414.605). For certain rural add-ons, section 1834(l) of the Act requires that we use the most recent version of the Goldsmith Modification to determine rural census tracts within MSAs. In the CY 2007 PFS final rule (71 FR 69714 through 69716), we adopted the most recent (at that time) version of the Goldsmith Modification, designated as Rural-Urban Commuting Area (RUCA) codes. RUCA codes use urbanization, population density, and daily commuting data to categorize every census tract in the country. For a discussion about RUCA codes, we refer the reader to the CY 2007 PFS final rule (71 FR 69714 through 69716). As stated previously, on February 28, 2013, OMB issued OMB Bulletin No. 13–01, which established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. Several modifications of the RUCA codes were necessary to take into account updated commuting data and the revised OMB delineations. We refer readers to the U.S. Department of Agriculture’s Economic Research Service Web site for a detailed listing of updated RUCA codes found at <http://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx>. The updated RUCA code definitions were introduced in late 2013 and are based on data from the 2010 decennial census and the 2006–10 American Community Survey. We proposed to adopt the most recent modifications of the RUCA codes beginning in CY 2015, to recognize

levels of rurality in census tracts located in every county across the nation, for purposes of payment under the ambulance fee schedule. In the CY 2015 PFS proposed rule (79 FR 40373), we stated that if we adopt the most recent RUCA codes, many counties that are designated as urban at the county level based on population would have rural census tracts within them that would be recognized as rural areas through our use of RUCA codes.

As we stated in the CY 2015 PFS proposed rule (79 FR 40373 through 40374), the 2010 Primary RUCA codes are as follows:

- (1) Metropolitan area core: primary flow with an urbanized area (UA).
- (2) Metropolitan area high commuting: primary flow 30 percent or more to a UA.
- (3) Metropolitan area low commuting: primary flow 10 to 30 percent to a UA.
- (4) Micropolitan area core: primary flow within an Urban Cluster of 10,000 to 49,999 (large UC).
- (5) Micropolitan high commuting: primary flow 30 percent or more to a large UC.
- (6) Micropolitan low commuting: primary flow 10 to 30 percent to a large UC.
- (7) Small town core: primary flow within an Urban Cluster of 2,500 to 9,999 (small UC).
- (8) Small town high commuting: primary flow 30 percent or more to a small UC.
- (9) Small town low commuting: primary flow 10 to 30 percent to a small UC.
- (10) Rural areas: primary flow to a tract outside a UA or UC.

Based on this classification, and consistent with our current policy (71 FR 69715), we proposed to continue to designate any census tracts falling at or above RUCA level 4.0 as rural areas for purposes of payment for ambulance services under the ambulance fee schedule. As discussed in the CY 2007 PFS final rule (71 FR 69715), the Office of Rural Health Policy within the Health Resources and Services Administration (HRSA) determines eligibility for its rural grant programs through the use of the RUCA code methodology. Under this methodology, HRSA designates any census tract that falls in RUCA level 4.0 or higher as a rural census tract. In addition to designating any census tracts falling at or above RUCA level 4.0 as rural areas, under the updated RUCA code definitions, HRSA has also designated as rural census tracts those census tracts with RUCA codes 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people. We refer readers to

HRSA's Web site: <ftp://ftp.hrsa.gov/ruralhealth/Eligibility2005.pdf> for additional information. Consistent with the HRSA guidelines discussed above, we proposed, beginning in CY 2015, to designate as rural areas (1) those census tracts that fall at or above RUCA level 4.0, and (2) those census tracts that fall within RUCA levels 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people. We stated in the CY 2015 PFS proposed rule (79 FR 40374) that we continue to believe that HRSA's guidelines accurately identify rural census tracts throughout the country, and thus would be appropriate to apply for ambulance payment purposes. We invited comments on this proposal.

We stated in the CY 2015 PFS proposed rule (79 FR 40374) that the adoption of the most current OMB delineations and the updated RUCA codes would affect whether certain areas are recognized as rural or urban. The distinction between urban and rural is important for ambulance payment purposes because urban and rural transports are paid differently. The determination of whether a transport is urban or rural is based on the point of pick-up for the transport, and thus a transport is paid differently depending on whether the point of pick-up is in an urban or a rural area. During claims processing, a geographic designation of urban, rural, or super rural is assigned to each claim for an ambulance transport based on the point of pick-up ZIP code that is indicated on the claim.

Currently, section 1834(l)(12) of the Act (as amended by section 104(b) of the PAMA) specifies that, for services furnished during the period July 1, 2004 through March 31, 2015, the payment amount for the ground ambulance base rate is increased by a "percent increase" (Super Rural Bonus) where the ambulance transport originates in a "qualified rural area," which is a rural area that we determine to be in the lowest 25th percentile of all rural populations arrayed by population density (also known as a "super rural area"). We implement this Super Rural Bonus in § 414.610(c)(5)(ii). We stated in the CY 2015 PFS proposed rule (79 FR 40374) that adoption of the revised OMB delineations and the updated RUCA codes would have no negative impact on ambulance transports in super rural areas, as none of the current super rural areas would lose their status due to the revised OMB delineations and the updated RUCA codes.

As we stated in the CY 2015 PFS proposed rule (79 FR 40374), the adoption of the new OMB delineations and the updated RUCA codes would

affect whether or not transports would be eligible for other rural adjustments under the ambulance fee schedule statute and regulations. For ground ambulance transports where the point of pick-up is in a rural area, the mileage rate is increased by 50 percent for each of the first 17 miles (§ 414.610(c)(5)(i)). For air ambulance services where the point of pick-up is in a rural area, the total payment (base rate and mileage rate) is increased by 50 percent (§ 414.610(c)(5)(i)). Furthermore, under section 1834(l)(13) of the Act (as amended by section 104(a) of the PAMA), for ground ambulance transports furnished through March 31, 2015, transports originating in rural areas are paid based on a rate (both base rate and mileage rate) that is 3 percent higher than otherwise is applicable. (See also § 414.610(c)(1)(ii)).

We stated in the CY 2015 PFS proposed rule (79 FR 40374) that if we adopt OMB's revised delineations and the updated RUCA codes, ambulance providers and suppliers that pick up Medicare beneficiaries in areas that would be Micropolitan or otherwise outside of MSAs based on OMB's revised delineations or in a rural census tract of an MSA based on the updated RUCA codes (but are currently within urban areas) may experience increases in payment for such transports because they may be eligible for the rural adjustment factors discussed above, while those ambulance providers and suppliers that pick up Medicare beneficiaries in areas that would be urban based on OMB's revised delineations and the updated RUCA codes (but are currently in Micropolitan Areas or otherwise outside of MSAs, or in a rural census tract of an MSA) may experience decreases in payment for such transports because they would no longer be eligible for the rural adjustment factors discussed above.

The use of the revised OMB delineations and the updated RUCA codes would mean the recognition of new urban and rural boundaries based on the population migration that occurred over a 10-year period, between 2000 and 2010. In the CY 2015 PFS proposed rule (79 FR 40374), we stated that, based on the latest United States Postal Service (USPS) ZIP code file, there are a total of 42,914 ZIP codes in the U.S. We stated in the proposed rule that the geographic designations for approximately 99.48 percent of ZIP codes would be unchanged by OMB's revised delineations and the updated RUCA codes, and that a similar number of ZIP codes would change from rural to urban (122, or 0.28 percent) as would change from urban to rural (100, or 0.23

percent). We stated in the proposed rule that, in general, it was expected that ambulance providers and suppliers in 100 ZIP codes within 11 states may experience payment increases if we adopt the revised OMB delineations and the updated RUCA codes, as these areas would be redesignated from urban to rural. We stated that the state of Ohio would have the most ZIP codes changing from urban to rural with a total of 40, or 2.69 percent. We also stated in the CY 2015 PFS proposed rule that ambulance providers and suppliers in 122 ZIP codes within 22 states may experience payment decreases if we adopt the revised OMB delineations and the updated RUCA codes, as these areas would be redesignated from rural to urban. We stated that the state of West Virginia would have the most ZIP codes changing from rural to urban (17, or 1.82 percent), while Connecticut would have the greatest percentage of ZIP codes changing from rural to urban (15 ZIP codes, or 3.37 percent). Our findings were illustrated in Table 17 of the CY 2015 PFS proposed rule (79 FR 40375).

We stated in the CY 2015 PFS proposed rule (79 FR 40375 and 40376) that we believe the most current OMB statistical area delineations, coupled with the updated RUCA codes, more accurately reflect the contemporary urban and rural nature of areas across the country, and that use of the most current OMB delineations and RUCA codes under the ambulance fee schedule would enhance the accuracy of ambulance fee schedule payments. We solicited comments on our proposal to implement the new OMB delineations and the updated RUCA codes as discussed above beginning in CY 2015, for purposes of payment under the Medicare ambulance fee schedule.

We received four comments from two associations representing ambulance service providers and suppliers and two ambulance suppliers on our proposal to implement the new OMB delineations and the updated RUCA codes for purposes of payment under the Medicare ambulance fee schedule. Those comments are summarized below along with our responses.

Comment: All of the commenters agreed with CMS that it is appropriate to adjust the geographic area designations periodically so that the ambulance fee schedule reflects population shifts.

Response: We appreciate the support of the commenters.

Comment: Commenters expressed concern that the analysis of the proposed modification in the CY 2015 PFS proposed rule did not describe the actual impact of the proposed change

because it did not take into account the most recent modifications to the RUCA codes. When these codes are applied, the commenters stated that there would be substantially more ZIP codes that would shift. The commenters estimated that more than 1,500 ZIP codes would shift from rural to urban and about three times the number of ZIP codes identified in the proposed rule would change from urban to rural. The commenters also stated that some ZIP codes would no longer have super rural status.

Response: The commenters are correct that the analysis published in the CY 2015 PFS proposed rule (see Table 17 (79 FR 40375)) presented the impact of the revised OMB delineations only and did not include the impact of the updated RUCA codes. We did not receive the ZIP code approximation of the 2010 RUCA codes file in time to be

included in our analysis in the proposed rule.

We have completed an updated analysis of both the revised OMB delineations and the updated RUCA codes. Based on the latest United States Postal Service (USPS) ZIP code file, there are a total of 42,918 ZIP codes in the U.S. Based on our updated analysis, we have concluded that the geographic designations for approximately 92.02 percent of ZIP codes would be unchanged by OMB's revised delineations and the updated RUCA codes. There are more ZIP codes that would change from rural to urban (3,038 or 7.08 percent) than from urban to rural (387 or 0.90 percent). The differences in the data provided in the proposed rule compared to the final rule are due to inclusion of the updated RUCA codes. In general, it is expected that ambulance providers and suppliers in 387 ZIP

codes within 41 states, may experience payment increases under the revised OMB delineations and the updated RUCA codes, as these areas have been redesignated from urban to rural. The state of California has the most ZIP codes changing from urban to rural with a total of 43, or 1.58 percent. Ambulance providers and suppliers in 3,038 ZIP codes within 46 states and Puerto Rico may experience payment decreases under the revised OMB delineations and the updated RUCA codes, as these areas have been redesignated from rural to urban. The state of Pennsylvania has the most ZIP codes changing from rural to urban (293, or 13.06 percent), while West Virginia has the greatest percentage of ZIP codes changing from rural to urban (269 ZIP codes, or 28.74 percent). Our findings are illustrated in Table 47.

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TABLE 47: Updated ZIP Codes Analysis Based on OMB's Revised Delineations and Updated RUCA Codes

State/ Territory*	Total ZIP Codes	Total ZIP Codes Changed Rural to Urban	Percentage of Total ZIP Codes	Total ZIP Codes Changed Urban to Rural	Percentage of Total ZIP Codes	Total ZIP Codes Not Changed	Percentage of Total ZIP Codes Not Changed
AK	276	0	0.00%	0	0.00%	276	100.00%
AL	854	83	9.72%	8	0.94%	763	89.34%
AR	725	41	5.66%	6	0.83%	678	93.52%
AS	1	0	0.00%	0	0.00%	1	100.00%
AZ	569	21	3.69%	7	1.23%	541	95.08%
CA	2723	94	3.45%	43	1.58%	2586	94.97%
CO	677	4	0.59%	9	1.33%	664	98.08%
CT	445	56	12.58%	0	0.00%	389	87.42%
DC	303	0	0.00%	0	0.00%	303	100.00%
DE	99	6	6.06%	0	0.00%	93	93.94%
EK	63	0	0.00%	0	0.00%	63	100.00%
EM	856	71	8.29%	2	0.23%	783	91.47%
FL	1513	105	6.94%	9	0.59%	1399	92.47%
FM	4	0	0.00%	0	0.00%	4	100.00%
GA	1032	101	9.79%	4	0.39%	927	89.83%
GU	21	0	0.00%	0	0.00%	21	100.00%
HI	143	9	6.29%	3	2.10%	131	91.61%
IA	1080	42	3.89%	3	0.28%	1035	95.83%
ID	335	3	0.90%	0	0.00%	332	99.10%
IL	1628	159	9.77%	7	0.43%	1462	89.80%
IN	1000	110	11.00%	7	0.70%	883	88.30%
KY	1030	81	7.86%	5	0.49%	944	91.65%
LA	739	101	13.67%	1	0.14%	637	86.20%
MA	751	14	1.86%	6	0.80%	731	97.34%
MD	630	84	13.33%	0	0.00%	546	86.67%
ME	505	19	3.76%	12	2.38%	474	93.86%
MH	2	0	0.00%	0	0.00%	2	100.00%
MI	1185	63	5.32%	13	1.10%	1109	93.59%
MN	1043	47	4.51%	7	0.67%	989	94.82%
MP	3	0	0.00%	0	0.00%	3	100.00%
MS	541	36	6.65%	1	0.18%	504	93.16%
MT	411	0	0.00%	3	0.73%	408	99.27%
NC	1101	163	14.80%	6	0.54%	932	84.65%
ND	419	2	0.48%	0	0.00%	417	99.52%
NE	632	7	1.11%	6	0.95%	619	97.94%
NH	292	6	2.05%	2	0.68%	284	97.26%
NJ	747	1	0.13%	2	0.27%	744	99.60%
NM	438	4	0.91%	2	0.46%	432	98.63%
NV	257	4	1.56%	2	0.78%	251	97.67%

State/ Territory*	Total ZIP Codes	Total ZIP Codes Changed Rural to Urban	Percentage of Total ZIP Codes	Total ZIP Codes Changed Urban to Rural	Percentage of Total ZIP Codes	Total ZIP Codes Not Changed	Percentage of Total ZIP Codes Not Changed
NY	2246	180	8.01%	42	1.87%	2024	90.12%
OH	1487	80	5.38%	34	2.29%	1373	92.33%
OK	791	23	2.91%	7	0.88%	761	96.21%
OR	495	26	5.25%	9	1.82%	460	92.93%
PA	2244	293	13.06%	38	1.69%	1913	85.25%
PR	177	21	11.86%	0	0.00%	156	88.14%
PW	2	0	0.00%	0	0.00%	2	100.00%
RI	91	2	2.20%	1	1.10%	88	96.70%
SC	543	91	16.76%	2	0.37%	450	82.87%
SD	418	0	0.00%	1	0.24%	417	99.76%
TN	814	82	10.07%	12	1.47%	720	88.45%
TX	2726	155	5.69%	32	1.17%	2539	93.14%
UT	359	2	0.56%	0	0.00%	357	99.44%
VA	1277	147	11.51%	13	1.02%	1117	87.47%
VI	16	0	0.00%	0	0.00%	16	100.00%
VT	309	15	4.85%	0	0.00%	294	95.15%
WA	744	29	3.90%	6	0.81%	709	95.30%
WI	919	66	7.18%	5	0.54%	848	92.27%
WK	711	16	2.25%	5	0.70%	690	97.05%
WM	342	4	1.17%	3	0.88%	335	97.95%
WV	936	269	28.74%	0	0.00%	667	71.26%
WY	198	0	0.00%	1	0.51%	197	99.49%
TOTALS	42918	3038	7.08%	387	0.90%	39493	92.02%

* ZIP code analysis includes U.S. States and Territories (FM- Federated States of Micronesia, GU – Guam, MH- Marshall Islands, MP-Northern Mariana Islands, PW- Palau, AS- American Samoa; VI- Virgin Islands; PR- Puerto Rico). [Missouri is divided into east and west regions due to work distribution of the Medicare Administrative Contractors (MACs) : EM- East Missouri, WM – West Missouri. Johnson and Wyandotte counties in Kansas were changed as of January 2010 to East Kansas (EK) and the rest of the state is West Kansas (WK).

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As discussed above, in the CY 2015 PFS proposed rule (79 FR 40374), we proposed to designate as rural those census tracts that fall in RUCA codes 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people. However, upon further analysis, we have determined that it is not feasible to implement this proposal. Payment under the ambulance fee schedule is based on the ZIP codes; therefore, if the ZIP code is predominantly metropolitan but has some rural census tracts, we do not split the ZIP code areas to distinguish further granularity to provide different payments within the same ZIP code. We believe that payment for all ambulance transportation services at the ZIP code

level provides a consistent payment system. Therefore, such census tracts were not considered rural areas in the updated analysis set forth above.

For more detail on the impact of these changes, in addition to Table 47, the following files are available through the Internet on the AFS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/index.html>: ZIP codes by state that changed from urban to rural, ZIP codes by state that changed from rural to urban, list of ZIP codes with RUCA code designations, and a complete list of ZIP codes identifying their designation as super rural, rural or urban.

As reflected in Table 47, our findings are generally consistent with the

commenters' findings that more than 1,500 ZIP codes would change from rural to urban (our updated analysis indicates that 3,038 ZIP codes are changing), and that about three times the number of ZIP codes identified in the proposed rule (100) would change from urban to rural (our updated analysis indicates 387 ZIP codes are changing).

As we stated in the proposed rule (79 FR 40374), none of the current super rural areas will lose their super rural status upon implementation of the revised OMB delineations and the updated RUCA codes.

Comment: One commenter suggested that we delay the implementation of the adjustment until CY 2016 to allow CMS sufficient time to publish the changes in

rural and urban status and allow all interested parties to provide comments on the proposal. In addition to delaying implementation, the commenter suggested implementing a 4-year transition that would phase-in the payment reduction over a specified period for those ZIP codes losing rural status.

Other commenters requested that the implementation of the geographic adjustments outlined in the proposed rule be delayed until such time as the data is available to complete a full and accurate analysis of the ZIP codes affected and the financial impact to industry. Absent such a delay, the commenters stated that the final rule must clarify, in a complete and transparent manner, the accuracy of the analysis used in the proposed rule.

Response: We believe that ambulance providers and suppliers had sufficient notice of and opportunity to comment on the proposed adoption of the revised OMB delineations and the updated RUCA codes under the ambulance fee schedule, and thus we do not believe a delay in implementation is warranted. In the proposed rule, we proposed to adopt the revised OMB delineations as set forth in OMB Bulletin No. 13–01 and the updated RUCA codes for purposes of payment under the ambulance fee schedule consistent with the policy we implemented in CY 2007 (see the CY 2007 PFS final rule (71 FR 69713 through 69716)). We explained in the proposed rule that the adoption of the revised OMB delineations and updated RUCA codes would affect the urban/rural designation of certain areas, and thus would affect whether transports in certain areas would be eligible for rural adjustments under the ambulance fee schedule. In addition, OMB Bulletin No. 13–01 was available on February 28, 2013, and contained additional information regarding the changes in OMB geographic area delineations. As discussed above, the ZIP code analysis set forth in the proposed rule reflected the impact of the revised OMB delineations. The 2010 RUCA codes and definitions were available on December 31, 2013 on the U.S. Department of Agriculture's Economic Research Service's Web site, which provided ambulance providers and suppliers with additional information regarding changes to the level of rurality in census tracts. Furthermore, section 1834(l) requires that we use the most recent modification of the Goldsmith Modification to determine rural census tracts for purposes of certain rural additions, and our established policy, as set forth in § 414.605, is that rural areas include rural census tracts as

determined under the most recent version of the Goldsmith modification.

As discussed above and in the CY 2015 PFS proposed rule, we believe the most current OMB statistical area delineations, coupled with the updated RUCA codes, more accurately reflect the contemporary urban and rural nature of areas across the country, and thus we believe the use of the most current OMB delineations and RUCA codes under the ambulance fee schedule will enhance the accuracy of ambulance fee schedule payments. We believe that it is important to use the most current OMB delineations and RUCA codes available as soon as reasonably possible to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts. Because we believe the revised OMB delineations and updated RUCA codes more accurately identify urban and rural areas and enhance the accuracy of the Medicare ambulance fee schedule, we do not believe a delay in implementation or a transition period would be appropriate. Areas that lose their rural status and become urban have become urban because of recent population shifts. We believe it is important to base payment on the most accurate and up-to-date geographic area delineations available. Furthermore, we believe a delay would disadvantage the ambulance providers or suppliers experiencing payment increases based on these updated and more accurate OMB delineations and RUCA codes.

Finally, given the relatively small percentage of ZIP codes affected by the revised OMB delineations and updated RUCA codes (a total of 3,425 ZIP codes changing their urban/rural status out of 42,918 ZIP codes, or 7.98 percent), we do not believe that a delay is warranted. As commenters requested, we have included in Table 47 our updated analysis of the impact of adopting the revised OMB delineations and the updated RUCA codes.

Comment: One commenter recommended that if any ZIP codes would lose their super rural status as a result of the proposed adoption of the revised OMB delineations and the updated RUCA codes, then CMS should grandfather the current super rural ZIP codes. Another commenter stated that the ambulance providers must have verification from CMS that the super rural ZIP codes will not be affected by the changes described in the proposed rule in advance of their implementation in the final rule.

Response: As we stated previously, the adoption of the OMB's revised delineations and the updated RUCA codes will have no negative impact on

ambulance transports in super rural areas, as none of the current super rural areas will lose their status upon implementation of the revised OMB delineations and the updated RUCA codes. Current areas designated as super rural areas will continue to be eligible for the super rural bonus.

After consideration of the public comments received, and for the reasons discussed above, we are finalizing our proposals to adopt, beginning in CY 2015, the revised OMB delineations as set forth in OMB's February 28, 2013 bulletin (No. 13–01) and the most recent modifications of the RUCA codes for purposes of payment under the ambulance fee schedule. As we proposed, using the updated RUCA codes definitions, we will continue to designate any census tracts falling at or above RUCA level 4.0 as rural areas. However, as discussed above, we are not finalizing our proposal to designate as rural those census tracts that fall within RUCA codes 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people. Finally, as discussed above, none of the current super rural areas will lose their super rural status upon implementation of the revised OMB delineations and the updated RUCA codes.

C. Clinical Laboratory Fee Schedule

In the CY 2014 PFS final rule with comment period (78 FR 74440 through 74445, 74820), we finalized a process under which we would reexamine the payment amounts for test codes on the Clinical Laboratory Fee Schedule (CLFS) for possible payment revision based on technological changes beginning with the CY 2015 proposed rule, and we codified this process at § 414.511. After we finalized this process, the Congress enacted the PAMA. Section 216 of the PAMA creates new section 1834A of the Act, which requires us to implement a new Medicare payment system for clinical diagnostic laboratory tests based on private payor rates. Section 216 of the PAMA also rescinds the statutory authority in section 1833(h)(2)(A)(i) of the Act for adjustments based on technological changes for tests furnished on or after April 1, 2014 (PAMA's enactment date). As a result of these provisions, we did not propose any revisions to payment amounts for test codes on the CLFS based on technological changes, and we proposed to remove § 414.511.

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal to remove § 414.511. In addition, we will establish through rulemaking the parameters for

the collection of private payor rate information and other requirements to implement section 216 of the PAMA.

D. Removal of Employment Requirements for Services Furnished “Incident to” Rural Health Clinics (RHC) and Federally Qualified Health Center (FQHC) Visits

1. Background

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) furnish physicians' services; services and supplies “incident to” the services of physicians: Nurse practitioner (NP), physician assistant (PA), certified nurse-midwife (CNM), clinical psychologist (CP), and clinical social worker (CSW) services; and services and supplies incident to the services of NPs, PAs, CNMs, CPs, and CSWs. They may also furnish diabetes self-management training and medical nutrition therapy (DSMT/MNT), transitional care management services, and in some cases, visiting nurse services furnished by a registered professional nurse or a licensed practical nurse. (For additional information on coverage requirements for services furnished in RHCs and FQHCs, see Chapter 13 of the CMS Benefit Policy Manual.)

In the May 2, 2014 final rule with comment period entitled “Prospective Payment System for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics; and Changes to Clinical Laboratory Improvement Amendments of 1988 Enforcement Actions for Proficiency Testing Referral” (79 FR 25436), we removed the regulatory requirements that NPs, PAs, CNMs, CSWs, and CPs furnishing services in a RHC must be employees of the RHC. RHCs are now allowed to contract with NPs, PAs, CNMs, CSWs, and CPs, as long as at least one NP or PA is employed by the RHC, as required under clause (iii) in the first sentence of the flush material following subparagraph (K) of section 1861(aa)(2) of the Act.

Services furnished in RHCs and FQHCs by nurses, medical assistants, and other auxiliary personnel are considered “incident to” a RHC or FQHC visit furnished by a RHC or FQHC practitioner. Sections 405.2413(a)(6), 405.2415(a)(6), and 405.2452(a)(6) currently state that services furnished incident to an RHC or FQHC visit must be furnished by an employee of the RHC or FQHC. Since there is no separate benefit under Medicare law that specifically authorizes payment to nurses, medical assistants, and other auxiliary personnel

for their professional services, they cannot bill the program directly and receive payment for their services, and can only be remunerated when furnishing services to Medicare patients in an “incident to” capacity.

To provide RHCs and FQHCs with as much flexibility as possible to meet their staffing needs, we proposed to revise § 405.2413(a)(5), § 405.2415(a)(5) and § 405.2452(a)(5) and delete § 405.2413(a)(6), § 405.2415(a)(6) and § 405.2452(a)(6) to remove the requirement that services furnished incident to an RHC or FQHC visit must be furnished by an employee of the RHC or FQHC, in order to allow nurses, medical assistants, and other auxiliary personnel to furnish “incident to” services under contract in RHCs and FQHCs. We believe that removing the requirements will provide RHCs and FQHCs with additional flexibility without adversely impacting the quality or continuity of care.

We received 23 comments on our proposal. The following is a summary of the comments received.

Comment: Most commenters were strongly in favor of removing these employment requirements. Several commenters stated that this flexibility will assist RHCs and FQHCs in increasing access to care, enable them to recruit highly qualified health professionals, and fill temporary staffing voids without adversely impacting the quality of care. Some commenters expressed concerns about maintaining professional standards, and others were concerned about the potential loss of benefits for contracted staff.

A few commenters stated that they support removal of the employment requirement, provided that RHC and FQHC auxiliary personnel are held to the same high professional standards for the quality of care, regardless of whether they are working under contract or as employees. Commenters also added that all members of a physician-led health care team should be enabled to perform medical interventions that they are capable of performing according to their education, training, licensure, and experience.

Response: The proposal to remove the requirement that auxiliary workers in RHCs and FQHCs be employees of the RHC or FQHC does not change either their professional standards of care or their scope of practice. Nurses, medical assistants, and other auxiliary personnel are expected to maintain their professional standards of care and furnish services in adherence to their scope of practice, regardless of whether they are employed or contracted by the RHC or FQHC.

Comment: Some commenters stated that although they understand the need for greater staffing flexibility, they were concerned about the potential loss of benefit packages to individuals that are contracted and not employed. The commenters questioned whether the issue was investigated or vetted, and how RHCs and FQHCs would compensate for this loss of compensation for individuals providing incident to services under contract rather than as an employee.

Response: We appreciate the concern that these commenters raised regarding the potential loss of benefit packages for contracted individuals; however, we do not regulate employment agreements or benefit packages for individuals working at RHCs and FQHCs.

After consideration of the public comments, we are finalizing this provision as proposed.

E. Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models

1. Background and Statutory Authority

Section 3021 of the Affordable Care Act amended the Social Security Act to include a new section 1115A, which established the Center for Medicare and Medicaid Innovation (Innovation Center). Section 1115A tasks the Innovation Center with testing innovative payment and service delivery models that could reduce program expenditures while preserving and/or enhancing the quality of care furnished to individuals under titles XVIII, XIX, and XXI of the Act. The Secretary is also required to conduct an evaluation of each model tested.

Evaluations will typically include quantitative and qualitative methods to assess the impact of the model on quality of care and health care expenditures. To comply with the statutory requirement to evaluate all models conducted under section 1115A of the Act, we will conduct rigorous quantitative analyses of the impact of the model test on health care expenditures, as well as an assessment of measures of the quality of care furnished under the model test. Evaluations will also include qualitative analyses to capture the qualitative differences between model participants, and to form the context within which to interpret the quantitative findings. Through the qualitative analyses, we will assess the experiences and perceptions of model participants, providers, and individuals affected by the model.

In the evaluations we use advanced statistical methods to measure

effectiveness. Our methods are intended to provide results that meet a high standard of evidence, even when randomization is not feasible. To successfully carry out evaluations of Innovation Center models, we must be able to determine specifically which individuals are receiving services from or are the subject of the intervention being tested by the entity participating in the model test. Identification of such individuals is necessary for a variety of purposes, including the construction of control groups against which model performance can be compared. In addition, to determine whether the observed impacts are due to the model being tested and not due to differences between the intervention and comparison groups, our evaluations will have to account for potential confounding factors at the individual level, which will require the ability to identify every individual associated with the model test, control or comparison groups, and the details of the intervention at the individual level.

Evaluations will need to consider such factors as outcomes, clinical quality, adverse effects, access, utilization, patient and provider satisfaction, sustainability, potential for the model to be applied on a broader scale, and total cost of care. Individuals receiving services from or who are the subjects of the intervention will be compared to clinically, socio-demographically, and geographically similar matched individuals along various process, outcome, and patient-reported measures. Research questions in a typical evaluation will include, but are not limited to, the following:

- *Clinical Quality:*

++ Did the model improve or have a negative impact on clinical process measures, such as adherence to evidence-based guidelines? If so, how, how much, and for which individuals?

++ Did the model improve or have a negative impact on clinical outcome measures, such as mortality rates, and the incidence and prevalence of chronic conditions? If so, how, how much, and for which individuals?

++ Did the model improve or have a negative impact on access to care? If so, how, how much, and for which individuals?

++ Did the model improve or have a negative impact on care coordination among providers? If so, how, how much, and for which individuals?

++ Did the model improve or have a negative impact on medication management? If so, how, how much, and for which individuals?

- *Patient Experience:*

++ Did the model improve or have a negative impact on patient-provider communication? If so, how, how much, and for which individuals?

++ Did the model improve or have a negative impact on patient experiences of care, quality of life, or functional status? If so, how, how much, and for which individuals?

- *Utilization/Expenditures:*

++ Did the model result in decreased utilization of emergency department visits, hospitalizations, and readmissions? If so how, how much, and for which individuals?

++ Did the model result in increased utilization of physician or pharmacy services? If so how, how much, and for which individuals?

++ Did the model result in decreased total cost of care? Were changes in total costs of care driven by changes in utilization for specific types of settings or health care services? What specific aspects of the model led to these changes? Were any savings due to improper cost-shifting to the Medicaid program?

To carry out this research we must have access to patient records not generally available to us. As such, we proposed to exercise our authority in section 1115A(b)(4)(B) of the Act to establish requirements for states and other entities participating in the testing of past, present, and future models under section 1115A of the Act to collect and report information that we have determined is necessary to monitor and evaluate such models. Thus, we proposed to require model participants, and providers and suppliers working under the models operated by such participants, to produce such individually identifiable health information and such other information as the Secretary identifies as being necessary to conduct the statutorily mandated research described above. Such research will include the monitoring and evaluation of such models. Further, we view engagement with other payers, both public and private, as a critical driver of the success of these models. CMS programs constitute only a share of any provider's revenue. Therefore, efforts to improve quality and reduce cost are more likely to be successful if efforts are aligned across payers. Section 1115A of the Act specifically allows the Secretary of Health and Human Services to consider, in selecting which models to choose for testing, "whether the model demonstrates effective linkage with other public sector or private sector payers." Multi-payer models, such as but not limited to the Comprehensive Primary Care model, will conduct

quality measurement across all patients regardless of payer in order to maximize alignment and increase efficiency. Construction of multi-payer quality measures requires the ability to identify all individuals subject to the model test regardless of payer. In addition, section 1115A also permits the Secretary to consider models that allow states to test and evaluate systems of all-payer payment reform for the medical care of residents of the state, including dual eligible individuals. Under the State Innovation Model (SIM), the Innovation Center is testing the ability for state governments to accelerate transformation. The premise of the SIM initiative is to support Governor-sponsored, multi-payer models that are focused on public and private sector collaboration to transform the state's payment and delivery system. States have policy and regulatory authorities, as well as ongoing relationships with private payers, health plans, and providers that can accelerate delivery system reform. SIM models must impact the preponderance of care in the state and are expected to work with public and private payers to create multi-payer alignment. The evaluation of SIM will include all populations and payers involved in the state initiative, which in many cases includes private payers. The absence of identifiable data from private payers would result in considerable limitations on the level of evaluation conducted. Therefore, under this authority, we also proposed to require the submission of identifiable health and utilization information for patients of private payers treated by providers/suppliers participating in the testing of a model under section 1115A of the Act when an explicit purpose of the model test is to engage private sector payers. This regulation will provide clear legal authority for Health Insurance Portability and Accountability Act (HIPAA) Covered Entities to disclose any required protected health information. Identifiable data submitted by entities participating in the testing of models under section 1115A of the Act will meet CMS Acceptable Risks Safeguards (ARS) guidelines. When data is expected to be exchanged over the internet, such exchange will also meet all E-Gov requirements. In accordance with the requirements of the Privacy Act of 1974, upon receipt by CMS or its contractors, these data will be covered under a CMS-established system of records (System No. 09-70-0591), which serves as the Master system for all demonstrations, evaluations, and research studies administered by the Innovation Center. These data will be

stored until the evaluation is complete and all necessary policy deliberations have been finalized.

2. Provisions of the Proposed Regulations

Wherever possible, evaluations will make use of claims, assessment, and enrollment data available through CMS' existing administrative systems. However, evaluations will generally also need to include additional data not available through existing CMS administrative systems. As such, depending on the particular project, CMS or its contractor will require the production of the minimum data necessary to carry out the statutorily mandated research work described in section E.1. of this final rule with comment period. Such data may include the identities of the patients served under the model, relevant clinical details about the services furnished and outcomes achieved, and any confounding factors that might influence the evaluation results achieved through the delivery of such services. For illustrative purposes, below are examples of some of the types of information that could be required to carry out an evaluation, and for which the evaluator would need patient-level identifiers.

- Utilization data not otherwise available through existing Centers for Medicare & Medicaid Services (CMS) systems.
- Beneficiary, patient, participant, family, and provider experiences.
- Beneficiary, patient, participant, and provider rosters with identifiers that allow linkages across time and datasets.
- Beneficiary, patient, participant, and family socio-demographic and ethnic characteristics.
- Care management details, such as details regarding the provision of services, payments or goods to beneficiaries, patients, participants, families, or other providers.
- Beneficiary, patient, and participant functional status and assessment data.
- Beneficiary, patient, and participant health behaviors.
- Clinical data, such as, but not limited to lab values and information from EHRs.
- Beneficiary, patient, participant quality data not otherwise available through claims.
- Other data relevant to identified outcomes—for example, participant employment status, participant educational degrees pursued/achieved, and income.

We invited public comment on this proposal to mandate the production of

the individually identifiable information necessary to conduct the statutorily mandated research under section 1115A of the Act.

In addition, we proposed a new subpart K in part 403 to implement section 1115A of the Act.

The following is a summary of the comments we received regarding our proposal to mandate the production of the individually identifiable information necessary to conduct the statutorily mandated research under section 1115A of the Act.

Comment: Commenters consistently recognized the need to evaluate Innovation Center models as an important component of the effort to test new payment and service delivery models. Further, several commenters supported the need for rigorous evaluations that include control groups. One commenter further recommended the Innovation Center make the aggregated de-identified data from evaluations available to external researchers. Although supportive of the need to evaluate Innovation Center models, several commenters stated the Innovation Center had not sufficiently justified the need for individually identifiable patient information, and suggested aggregate or de-identified data should be sufficient. One commenter suggested the submission of performance rates, patient outcomes information, and/or composite scores for participating providers instead of individual patient-level data. The commenter further stated that CMS should not have access to proprietary patient-level data in registries. Some of the commenters stated CMS should publish its evaluation methodologies and solicit feedback from independent research experts as to the need for patient-level data.

Response: We appreciate the commenters' support for rigorous evaluations, and understand the desire for access to the aggregate de-identified data from these evaluations. We always make our data available in accordance with applicable law, HHS and CMS policies, and, where relevant, the availability of funding. Such laws include HIPAA, the Privacy Act, the Trade Secrets Act and the Freedom of Information Act. With respect to comments recommending the use of aggregate or de-identified data instead of individually identifiable data, as we discussed in the preamble of the proposed rule, we believe individually identifiable data is necessary. As noted in this final rule with comment and in the preamble of our proposed rule, evaluations will need to consider such factors as outcomes, clinical quality,

adverse effects, access, utilization, patient and provider satisfaction, sustainability, potential for the model to be applied on a broader scale, and total cost of care. Furthermore, individuals receiving services from or who are the subjects of the intervention will be compared to clinically, socio-demographically, and geographically similar matched individuals along various process, outcome, and patient-reported measures. Many of these assessments will require person-level data. We will make use of aggregate information on system performance through the use of provider submitted aggregate performance rates for selected measures, patient outcomes information, and/or composite scores. However, without the ability to identify specifically which beneficiaries are receiving services as a result of the model, the evaluation analyses could include individuals not even subject to the intervention, and therefore, there would be a very real possibility that positive impacts of the model may be diluted and unobservable. While aggregate data could be limited to the target population, identification of which individuals are within the target population of the model, are receiving items and services under the model, or are subject to the interventions being tested under the model will also allow the evaluators to construct matched comparison groups that look as similar as possible to the intervention group. The absence of a well-matched comparison group, which can only be achieved when individually identifiable characteristics are known, could result in impact estimates that are inaccurate because these impact estimates could be due to differences between the intervention group and the comparison group and not the intervention itself. Further, while we will need to know the identifiers of beneficiaries that are the subject of the model test, the submission of other patient-level data from proprietary registries would be limited to data necessary to conduct a credible evaluation. Data on individuals are also needed to assess differential impacts among subgroups of beneficiaries to identify who benefits most from the intervention. We agree it is important to seek expert opinion on the structure of our assessment methods, and so these models are developed in concert with and run through our evaluation contractors, which are independent research firms and academic institutions. Where needed, these contractors also reach out to technical expert panels for added guidance. As a result, the design and implementation of

these assessments are informed by those with expertise in health services research, economics, statistics, program evaluation, epidemiology, and public health.

Comment: Although generally supportive of the need for rigorous evaluations, some commenters worried that any requirement to provide individually identifiable data for monitoring and/or assessment purposes would impose an undue administrative burden on model participants, and could lead to the need to submit large (and, potentially, overbroad) amounts of individually identifiable patient-level data. A few commenters suggested that the Innovation Center should first look to other federal government sources before requesting data from model participants. Several commenters noted that it would be costly to produce patient-level data for models with a multi-payer focus, and others stated additional payment should be made to model participants to offset the cost of data reporting. Further, it was suggested that CMS estimate the potential burden and cost on physicians and other providers, and if found to be burdensome, give physicians the right to opt out of producing information that may not be available due to cost limitations or other administrative barriers, such as barriers to producing data stored in electronic health records.

Response: We agree that our determination of what data are necessary to evaluate a model should be made taking into consideration the burden and cost associated with collecting and reporting such data, including the complexities associated with abstracting data from electronic health records. We further agree that in making such determinations, we should take advantage of all existing federal data systems, wherever possible so that we may minimize the amount of data that we must obtain from model participants. Our regulation will only require that model participants collect and report data as is necessary for monitoring or evaluation; thus, if we do not need the data, we would not seek to collect it from model participants.

Reimbursement may be considered for future models, but if adopted, any such reimbursement, and any conditions for such reimbursement, would be prominently noted in the solicitation or modifications to model agreements. To the extent feasible, we also agree that it is important for potential model participants to understand the data collection requirements before the model begins, so that they may take these requirements into consideration. We do not agree, though, that model

participants should be given the opportunity to opt out of producing the required information, as this would undermine the evaluation and skew results.

With respect to the specific data needed for evaluation purposes, in many models, the evaluators will be able to determine who the individuals are that are the subjects of the model test without the need to obtain identifiers from the model participants. In those cases, there is a beneficiary-specific payment under the model and the evaluator can use our existing administrative data systems to identify which beneficiaries are in the model. In this last example, although we may not need to obtain the identifiers, we may still need to obtain other person-level data, such as clinical information. In other models, where a specific beneficiary-level payment is not being made, the evaluation contractor will not have an ability to identify the individuals targeted by the model participants. In this latter circumstance, the participants will need to provide the identifiers that would then be used by the evaluator to link to existing administrative data systems. Although the exact data needs will vary by model, in some cases we would determine that only the identifiers (such as, but not limited to, the Medicare Health Insurance Claim number) are required. In other circumstances, it is possible the evaluators will need other data, such as clinical data not otherwise available in claims to properly account for severity of disease. In this manner we will limit data demands, and the attendant costs, to the data necessary to accomplish the required monitoring and assessment.

Comment: Some commenters stated the requirement could result in requests for data from providers tangentially involved in an Innovation Center project to report any data the agency decides it needs. A few commenters further stated the Innovation Center should ensure that all participating entities seek patient authorizations to use their records for the purpose of evaluating the model.

Response: Section 1115A(b)(4) of the Act authorizes us to establish requirements for “States and other entities participating in the testing of models” to collect and report data necessary for monitoring and evaluating the models. Our regulation, therefore, establishes this requirement only with respect to model participants. We consider model participants to include any party that has agreed to participate in, or that receives payment from us under, a model we are testing. In response to the comment suggesting that

the Innovation Center ensure that all participating entities seek patient authorizations to use their records for the purpose of evaluating the model, we decline to impose such a requirement in implementing section 1115A(b)(4) of the Act, and we refer such entities to their own legal counsel for advice on whether any form of consent would be required by other applicable law.

Comment: Some commenters stated the Innovation Center should publish and be transparent about what the exact data reporting and collection requirements would be so that participants would have notice of what data they would be required to collect. Commenters stated that without a notice and comment period as part of the model test, there will be no opportunity for stakeholders to weigh in with their perspective of what constitutes the minimum necessary information to achieve the evaluation goals. A few commenters stated the Innovation Center should first determine the specific data elements that are required for evaluation purposes for the existing programs and this information should be shared with participants who should, at minimum, be given an opportunity to provide comment on the required inputs for which they will be responsible as part of the evaluation. These commenters also stated the Innovation Center should develop such requirements in advance of the program start for participants to allow them an opportunity to provide feedback and weigh the information as part of their decision to participate in the model.

Response: We agree it is important to restrict data requests to the data necessary to conduct credible monitoring and evaluation. We frequently provide stakeholders the opportunity to weigh in on what data they believe would be necessary to evaluate a model, generally through webinars that we conduct during model development and implementation. Further, in order for potential model participants to understand the likely data reporting requirements, to the extent feasible, these requirements are incorporated into the solicitation process. However, we decline to adopt a requirement to undertake a notice and comment process as part of our determination of what data are necessary for monitoring or evaluation because we believe the process already in place allows for model participant feedback. We also disagree with commenters who recommend that we make the determination and specify the particular data elements that will be required for monitoring and evaluation prior to the start of the model. It is not

always possible at that early stage of the model to know precisely what data elements will be necessary. However, we will strive to provide as much relevant detail as possible about data collection and reporting requirements in any solicitation process and in any ongoing communications with potential participants, and we will continue to take any comments received into account in determining our data needs.

Comment: A few commenters stated that CMS has not provided sufficient assurances that providers, in responding to these data requests, would be protected or deemed to be in compliance with the HIPAA requirements for the use and disclosure of protected health information (PHI). These commenters stated the Innovation Center reference to requiring reporting of individually identifiable patient-level data raises significant privacy concerns for providers who would be required to report such data. These commenters stated HIPAA requires that providers limit the use and disclosure of personal health information to the minimum necessary to accomplish the intended purpose of the disclosure. These commenters stated the Innovation Center requests for such data must be in compliance with providers' HIPAA obligations. As such, some commenters stated CMS should work with the Office for Civil Rights (OCR) to ensure providers reporting data as part of an evaluation are doing so consistent with their HIPAA obligations. These commenters stated it is HHS's Office for Civil Rights (OCR)—not CMS—that ultimately determines whether a particular provider is properly compliant and not subject to penalties. These same commenters suggested that the Innovation Center should work with OCR to issue OCR guidance stating that providers reporting data as part of an evaluation are doing so consistent with their HIPAA obligations. Some commenters stated CMS should consider the necessary data elements on a program-by-program basis rather than establishing a blanket approval, or at minimum limit the scope of the approved data requirements and uses, and should provide clear instructions and other educational resources to ensure that collection and reporting of the data complies with the HIPAA Privacy and Security rules.

Response: We appreciate the concerns expressed about compliance with the HIPAA requirements and the recommendation to work with OCR. However, we respectfully disagree that sufficient assurances have not been provided. The disclosure would be required by a regulation, so it would be

“required by law” under HIPAA. See 45 CFR 164.512(a) and the definition of “required by law” at 45 CFR 164.103. A HIPAA covered entity is permitted to disclose protected health information as required by law under these provisions so long as the disclosure complies with and is limited to the relevant requirements of the law. A separate minimum data necessary determination is not required under the HIPAA Privacy Rule for required by law disclosures under 45 CFR 164.512(a). See 45 CFR 164.502(b)(2). Although a separate minimum data necessary determination is not required, as a policy matter and consistent with the statutory authority under 1115A(b)(4), CMS will only require that data we determine is necessary for evaluation and monitoring of Innovation Center models.

Comment: Several commenters stated that collection of beneficiary-level health information raises significant security concerns. Although supportive of sharing relevant and medically necessary patient information, one commenter raised a particular concern that some data could be sensitive information related to mental health or substance abuse. Some commenters stated CMS should adopt safeguards against inappropriate use or disclosure of patient identifiable data.

Response: We agree that it is critical to abide by rigorous security standards, and we take patient privacy seriously. As CMMI is part of Fee-for-Service Medicare, a Health Care Component that is subject to the HIPAA requirements, providers' and suppliers' data will generally be subject to the same HIPAA privacy and security requirements as that data was subject to in the hands of the providers and suppliers from which it came. Furthermore, if stored in a manner searchable by individual identifiers, it will also be subject to the Privacy Act of 1974.

As HIPAA Business Associates, this data will be equally well protected when held by one of our evaluation contractors. In addition, the disclosure of substance abuse records will, where applicable, also be subject to the Part 2 regulations.

Comment: One commenter stated CMS should not use these data for purposes other than those articulated in the proposed rule, and that the assessments should comply with the applicable statutory requirements, meaning that: (1) The assessments should take into account all of the factors outlined under section 1115A(b)(4) of the Act (that is, quality of care, including patient-level outcomes and patient-centeredness

criteria); (2) the assessments should be made publicly available; and (3) CMS should pursue notice-and-comment rulemaking before any of the CMS demonstrations are expanded based on these assessments, as required by section 1115A(c) of the Act.

Response: We agree that evaluations should assess quality of care, and the patient-de-identified results should be made publicly available, as required by section 1115A(b)(4) of the Act. We would pursue model expansion according to the terms of the statute.

After consideration of the public comments we received, we are finalizing our proposal to mandate the production of the individually identifiable information necessary to conduct the statutorily mandated research under section 1115A of the Act. We are accepting the recommendations made by commenters to minimize participant burden, seek input from providers, and use independent researchers. In addition, we are finalizing our proposal to add a new subpart K in part 403 to implement section 1115A of the Act without modification.

F. Local Coverage Determination Process for Clinical Diagnostic Laboratory Testing

The CY 2015 proposed rule (79 FR 40378 through 40380), section III.F., included discussion of a proposal to modify the existing process used by the Medicare Administrative Contractors (MACs) in developing local coverage determinations (LCDs) for clinical diagnostic laboratory tests. Briefly, the proposal would have expedited the timeline for LCD development for clinical diagnostic laboratory test LCDs by reducing the calendar days for some of the steps and by making optional or eliminating other steps within the current process. A detailed discussion of the proposal is available in section III.F. of the CY 2015 PFS Proposed Rule.

We would like to thank the numerous public commenters for their time in submitting thoughtful comments to the agency on this issue. Comments were received from individual members of the public, insurers, drug manufacturers, medical specialty societies, laboratory groups and individual laboratories. The commenters focused their comments on the following issues: The proposal to reduce the draft LCD public comment period to 30 days; the proposal for a meeting of the Carrier Advisory Committee to be optional; the proposal to remove the requirement for a public meeting; and the proposal to eliminate the 45-day notice period prior to final

LCDs becoming effective. In addition, commenters were concerned about the proposed changes in light of section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), titled “Improving Medicare Policies for Clinical Diagnostic Laboratory Tests.” The comments received have given the agency much to consider prior to moving forward with any changes to the LCD process; therefore, we will not finalize any changes to the LCD process in this final rule. We will explore the possibility of future notice-and-comment rulemaking on this issue.

G. Private Contracting/Opt-Out

1. Background

Effective January 1, 1998, section 1802(b) of the Act permits certain physicians and practitioners to opt-out of Medicare if certain conditions are met, and to furnish through private contracts services that would otherwise be covered by Medicare. For those physicians and practitioners who opt-out of Medicare in accordance with section 1802(b) of the Act, the mandatory claims submission and limiting charge rules of section 1848(g) of the Act would not apply. As a result, if the conditions necessary for an effective opt-out are met, physicians and practitioners are permitted to privately contract with Medicare beneficiaries and to charge them without regard to Medicare’s limiting charge rules. Regulations governing the requirements and procedures for private contracts appear at 42 CFR part 405, subpart D.

a. Opt-Out Determinations (§ 405.450)

The private contracting regulation at § 405.450 describes certain opt-out determinations made by Medicare, and the process that physicians, practitioners, and beneficiaries may use to appeal those determinations. Section 405.450(a) describes the process available for physicians or practitioners to appeal Medicare enrollment determinations related to opting out of the program, and § 405.450(b) describes the process available to challenge payment determinations related to claims for services furnished by physicians who have opted out. Both provisions refer to § 405.803, the Part B claims appeals process that was in place at the time the opt-out regulations were issued (November 2, 1998). When those regulations were issued, a process for a physician or practitioner to appeal enrollment related decisions had not been implemented in regulation. Thus, to ensure an appeals process was available to physicians and practitioners for opt-out related issues, we chose to

utilize the existing claims appeals process in § 405.803 for both enrollment and claims related appeals.

In May 16, 2012 **Federal Register** (77 FR 29002), we published a final rule entitled “Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction.” In that final rule, we deleted the provisions relating to initial determinations, appeals, and reopenings of Medicare Part A and Part B claims, and relating to determinations and appeals regarding an individual’s entitlement to benefits under Medicare Part A and Part B, which were contained in part 405, subparts G and H (including § 405.803) because these provisions were obsolete and had been replaced by the regulations at part 405, subpart I. We inadvertently neglected to revise the cross-reference in § 405.450(a) and (b) of the private contracting regulations to direct appeals of opt-out determinations through the current appeal process. However, it is important to note that our policy regarding the appeal of opt-out determinations did not change when the appeal regulations at part 405, subpart I were finalized.

The procedures set forth in current part 498 establish the appeals procedures regarding decisions made by Medicare that affect enrollment in the program. We believe this process, and not the appeal process in part 405, subpart I, is the appropriate channel for physicians and practitioners to challenge an enrollment related opt-out decision made by Medicare. There are now two different sets of appeal regulations for initial determinations; and the appeal of enrollment related opt-out determinations is more like the types of determinations now addressed under part 498 than those under part 405, subpart I. Specifically, the appeal process under part 405, subpart I focuses on reviews of determinations regarding beneficiary entitlement to Medicare and claims for benefits for particular services. The appeal process under part 498 is focused on the review of determinations regarding the participation or enrollment status of providers and suppliers. Enrollment related opt-out determinations involve only the status of particular physician or practitioners under Medicare, and do not involve beneficiary eligibility or claims for specific services. As such, the appeal process under part 498 is better suited for the review of enrollment related opt-out determinations.

However, we do not believe the enrollment appeals process established in part 498 is the appropriate mechanism for challenging payment

decisions on claims for services furnished by a physician and practitioner who has opted out of the program. Appeals for such claims should continue to follow the appeals procedures now set forth in part 405 subpart I.

b. Definitions, Requirements of the Opt Out Affidavit, Effects of Opting Out of Medicare, Application to Medicare Advantage Contracts (§§ 405.400, 405.420(e), 405.425(a), and 405.455)

Section 405.400 sets forth certain definitions for purposes of the private contracting regulations. Among the defined terms is “Emergency care services” which means services furnished to an individual for treatment of an “emergency medical condition” as that term is defined in § 422.2. The cross-referenced regulation at § 422.2 included within the definition of emergency care services was deleted on June 29, 2000 (65 FR 40314) and at that time we inadvertently neglected to revise that cross-reference. The cross-reference within the definition of emergency care services should have been amended at that time to cite the definition of “emergency services” in § 424.101.

The private contracting regulations at § 405.420(e), § 405.425(a) and § 405.455 all use the term Medicare+Choice when referring to Part C plans. However, we no longer use the term Medicare+Choice when referring to Part C plans; instead the plans are referred to as Medicare Advantage plans. When part 422 of the regulations was updated on January 28, 2005 (70 FR 4741), we inadvertently neglected to revise § 405.420(e), § 405.425(a) and § 405.455 to replace the term Medicare+Choice with Medicare Advantage plan.

2. Provisions of the Proposed Regulation

For the reasons discussed above, we proposed that a determination described in § 405.450(a) (relating to the status of opt-out or private contracts) is an initial determination for purposes of § 498.3(b), and a physician or practitioner who is dissatisfied with a Medicare determination under § 405.450(a) may utilize the enrollment appeals process currently available for providers and suppliers in part 498. In addition, we proposed that a determination described in § 405.450(b) (that payment cannot be made to a beneficiary for services furnished by a physician or practitioner who has opted out) is an initial determination for the purposes of § 405.924 and may be challenged through the existing claims appeals procedures in part 405 subpart I. Accordingly, we proposed that the cross

reference to § 405.803 in § 405.450(a) be replaced with a cross reference to § 498.3(b). We also proposed that the cross reference to § 405.803 in § 405.450(b) be replaced with a cross reference to § 405.924. We also proposed corresponding edits to § 498.3(b) and § 405.924 to note that the determinations under § 405.450(a) and (b), respectively, are initial determinations.

For the reasons discussed above, we also proposed that the definition of Emergency care services at § 405.400 be revised to cite the definition of Emergency services in § 424.101 and that all references to Medicare+Choice in § 405.420(e), § 405.425(a) and § 405.455 be replaced with the term “Medicare Advantage.”

The following is a summary of the comments we received regarding our proposals.

Comment: Commenters requested that physicians and practitioners be allowed to opt out of Medicare indefinitely instead of submitting a new affidavit every 2 years.

Response: These comments are outside the scope of this rule as they are not related to the proposed changes to the opt-out regulations. Nevertheless, we note that section 1802(b)(3)(B)(ii) of the Act specifies that the opt-out affidavit must provide that the “physician or practitioner will not submit any claim under this title for any item or service provided to any Medicare beneficiary. . . during the 2-year period beginning on the date the affidavit is signed.” As such, the longest interval for which an opt-out can be effective is 2 years. We have no authority to modify that statutory requirement.

Because we did not receive any comments on our proposals, we are finalizing the rule as proposed.

H. Solicitation of Comments on the Payment Policy for Substitute Physician Billing Arrangements

1. Background

In accordance with section 1842(b)(6) of the Act, no payment under Medicare Part B may be made to anyone other than to the beneficiary to whom a service was furnished or to the physician or other person who furnished the service. However, there are certain limited exceptions to this general prohibition. For example, section 1842(b)(6)(D) of the Act describes an exception for substitute physician billing arrangements, which states that “payment may be made to a physician for physicians’ services (and services furnished incident to such

services) furnished by a second physician to patients of the first physician if (i) the first physician is unavailable to provide the services; (ii) the services are furnished pursuant to an arrangement between the two physicians that (I) is informal and reciprocal, or (II) involves per diem or other fee-for-time compensation for such services; (iii) the services are not provided by the second physician over a continuous period of more than 60 days or are provided over a longer continuous period during all of which the first physician has been called or ordered to active duty as a member of a reserve component of the Armed Forces; and (iv) the claim form submitted to the [Medicare Administrative contractor (MAC)] for such services includes the second physician’s unique identifier . . . and indicates that the claim meets the requirements of this subparagraph for payment to the first physician.” Section 1842(b)(6) of the Act is self-implementing and we have not interpreted the statutory provisions through regulations.

In practice, section 1842(b)(6)(D) of the Act generally allows for two types of substitute physician billing arrangements: (1) An informal reciprocal arrangement where doctor A substitutes for doctor B on an occasional basis and doctor B substitutes for doctor A on an occasional basis; and (2) an arrangement where the services of the substitute physician are paid for on a per diem basis or according to the amount of time worked. Substitute physicians in the second type of arrangement are sometimes referred to as “locum tenens” physicians. It is our understanding that locum tenens physicians are substitute physicians who often do not have a practice of their own, are geographically mobile, and work on an as-needed basis as independent contractors. They are utilized by physician practices, hospitals, and health care entities enrolled in Part B as Medicare suppliers to cover for physicians who are absent for reasons such as illness, pregnancy, vacation, or continuing medical education. Also, we have heard anecdotally that locum tenens physicians are used to fill staffing needs (for example, in physician shortage areas) or, on a temporary basis, to replace physicians who have permanently left a medical group or employer.

We are concerned about the operational and program integrity issues that result from the use of substitute physicians to fill staffing needs or to replace a physician who has

permanently left a medical group or employer. For example, although our Medicare enrollment rules require physicians and physician groups or organizations to notify us promptly of any enrollment changes (including reassignment changes) (see § 424.516(d)), processing delays or miscommunication between the departing physician and his or her former medical group or employer regarding which party would report the change to Medicare could result in the Provider Transaction Access Number (PTAN) that links the departed physician and his or her former medical group remaining “open” or “attached” for a period of time. During such period, both the departed physician and the departed physician’s former medical group might bill Medicare under the departed physician’s National Provider Identifier (NPI) for furnished services. This could occur where a substitute physician is furnishing services in place of the departed physician in the departed physician’s former medical group, while the departed physician is also furnishing services to beneficiaries following departure from the former group. Operationally, either or both types of claims could be rejected or denied, even though the claims filed by the departed physician were billed appropriately. Moreover, the continued use of a departed physician’s NPI to bill for services furnished to beneficiaries by a substitute physician raises program integrity issues, particularly if the departed physician is unaware of his or her former medical group or employer’s actions.

Finally, as noted above, section 1842(b)(6)(D)(iv) of the Act requires that the claim form submitted to the MAC include the substitute physician’s unique identifier. Currently, the unique identifier used to identify a physician is the physician’s NPI. Prior to the implementation of the NPI, the Unique Physician Identification Number (UPIN) was used. Because a substitute physician’s NPI is not captured on the CMS-1500 claim form or on the appropriate electronic claim, physicians and other entities that furnish services to beneficiaries through the use of a substitute physician are required to enter a modifier on the CMS-1500 claim form or on the appropriate electronic claim indicating that the services were furnished by a substitute physician; and to keep a record of each service provided by the substitute physician, associated with the substitute physician’s UPIN or NPI; and to make this record available to the MAC upon request. (See Medicare Claims

Processing Manual (Pub. 100–4), Chapter 1, Sections 30.2.10 and 30.2.11) However, having a NPI or UPIN does not necessarily mean that the substitute physician is enrolled in the Medicare program. Without being enrolled in Medicare, we do not know whether the substitute physician has the proper credentials to furnish the services being billed under section 1842(b)(6)(D) of the Act or if the substitute physician is sanctioned or excluded from Medicare. The importance of enrollment and the resulting transparency afforded the Medicare program and its beneficiaries was recognized by the Congress when it included in the Affordable Care Act a requirement that physicians and other eligible non-physician practitioners (NPPs) enroll in the Medicare program if they wish to order or refer certain items or services for Medicare beneficiaries. This includes those physicians and other eligible NPPs who do not and will not submit claims to a Medicare contractor for the services they furnish. We solicited comments regarding how to achieve similar transparency in the context of substitute physician billing arrangements for the identity of the individual actually furnishing the service to a beneficiary.

2. Analysis of Comments

To help inform our decision whether and, if so, how to address the issues discussed in section III.H.1., and whether to adopt regulations interpreting section 1842(b)(6)(D) of the Act, we solicited comments on the policy for substitute physician billing arrangements. We noted that any regulations would be proposed in a future rulemaking with opportunity for public comment. Through this solicitation, we hoped to understand better current industry practices for the use of substitute physicians and the impact that policy changes limiting the use of substitute physicians might have on beneficiary access to physician services.

We received a few comments on the issues raised in this solicitation. We thank the commenters for their input, and we will carefully consider their comments in any future rulemaking on this subject.

I. Reports of Payments or Other Transfers of Value to Covered Recipients

1. Background

In the February 8, 2013 **Federal Register** (78 FR 9458), we published the “Transparency Reports and Reporting of Physician Ownership or Investment Interests” final rule which implemented

section 1128G of the Social Security Act (“Act”), as added by section 6002 of the Affordable Care Act. Under section 1128G(a)(1) of the Act, manufacturers of covered drugs, devices, biologicals, and medical supplies (applicable manufacturers) are required to submit on an annual basis information about certain payments or other transfers of value made to physicians and teaching hospitals (collectively called covered recipients) during the course of the preceding calendar year. Section 1128G(a)(2) of the Act requires applicable manufacturers and applicable group purchasing organizations (GPOs) to disclose any ownership or investment interests in such entities held by physicians or their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. The implementing regulations are at 42 CFR part 402, subpart A, and part 403, subpart I. We have organized these reporting requirements under the “Open Payments” program.

The Open Payments program creates transparency around the nature and extent of relationships that exist between drug, device, biologicals and medical supply manufacturers, and physicians and teaching hospitals (covered recipients and physician owner or investors). The implementing regulations, which describe procedures for applicable manufacturers and applicable GPOs to submit electronic reports detailing payments or other transfers of value and ownership or investment interests provided to covered recipients and physician owners or investors, are codified at § 403.908.

Since the publication and implementation of the February 8, 2013 final rule, various stakeholders have provided feedback to CMS regarding certain aspects of these reporting requirements. Specifically, § 403.904(g)(1) excludes the reporting of payments associated with certain continuing education events, and § 403.904(c)(8) requires reporting of the marketed name for drugs and biologicals but makes reporting the marketed name of devices or medical supplies optional. We proposed a change to § 403.904(g) to correct an unintended consequence of the current regulatory text. Additionally, at § 403.904(c)(8), we proposed to make the reporting requirements consistent by requiring the reporting of the marketed name for drugs, devices, biologicals, or medical supplies which are associated with a payment or other transfer of value.

Additionally, at § 403.902, we proposed to remove the definition of a “covered device” because we believe it is duplicative of the definition of “covered drug, device, biological or medical supply” which is codified in the same section. We also proposed to require the reporting of the following distinct forms of payment: stock; stock option; or any other ownership interests specified in § 403.904(d)(3) to collect more specific data regarding the forms of payment.

2. Continuing Education Exclusion (§ 403.904(g)(1))

In the February 8, 2013 final rule, many commenters recommended that accredited or certified continuing education payments to speakers should not be reported because there are safeguards already in place, and they are not direct payments to a covered recipient. In the final rule preamble, we noted that “industry support for accredited or certified continuing education is a unique relationship” (78 FR 9492). Section 403.904(g)(1) states that payments or other transfers of value provided as compensation for speaking at a continuing education program need not be reported if the following three conditions are met:

- The event at which the covered recipient is speaking must meet the accreditation or certification requirements and standards for continuing education for one of the following organizations: the Accreditation Council for Continuing Medical Education (ACCME); the American Academy of Family Physicians (AAFP); the American Dental Association’s Continuing Education Recognition Program (ADA CERP); the American Medical Association (AMA); or the American Osteopathic Association (AOA).

- The applicable manufacturer does not pay the covered recipient speaker directly.

- The applicable manufacturer does not select the covered recipient speaker or provide the third party (such as a continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers for the continuing education program.

Since the implementation of § 403.904(g)(1), other accrediting organizations have requested that payments made to speakers at their events also be exempted from reporting. These organizations have stated that they follow the same accreditation standards as the organizations specified in § 403.904(g)(1)(i). Other stakeholders have recommended that the exemption be removed in its entirety stating

removal of the exclusion will allow for consistent reporting for compensation provided to physician speakers at all continuing education events, as well as transparency regarding compensation paid to physician speakers. Many stakeholders raised concerns that the reporting requirements are inconsistent because certain continuing education payments are reportable, while others are not. CMS' apparent endorsement or support to organizations sponsoring continuing education events was an unintended consequence of the final rule.

After consideration of these comments, we proposed to remove the language in § 403.904(g) in its entirety, in part because it is redundant with the exclusion in § 403.904(i)(1). That provision excludes indirect payments or other transfers of value where the applicable manufacturer is "unaware" of, that is, "does not know," the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year. When an applicable manufacturer or applicable GPO provides funding to a continuing education provider, but does not either select or pay the covered recipient speaker directly, or provide the continuing education provider with a distinct, identifiable set of covered recipients to be considered as speakers for the continuing education program, CMS will consider those payments to be excluded from reporting under § 403.904(i)(1). This approach is consistent with our discussion in the preamble to the final rule, in which we explained that if an applicable manufacturer conveys "full discretion" to the continuing education provider, those payments are outside the scope of the rule (78 FR 9492). In contrast, for example, when an applicable manufacturer conditions its financial sponsorship of a continuing education event on the participation of particular covered recipients, or pays a covered recipient directly for speaking at such an event, those payments are subject to disclosure.

We considered two alternative approaches to address this issue. First, we explored expanding the list of organizations in § 403.904(g)(1)(i) by name; however, we believe that this approach might imply CMS's endorsement of the named continuing education providers over others. Second, we considered expansion of the organizations in § 403.904(g)(1)(i) by articulating accreditation or certification standards that would allow a CME program to qualify for the exclusion. This approach is not easily

implemented because it would require evaluating both the language of the standards, as well as the enforcement of the standards of any organization professing to meet the criteria. We solicited comments on both alternatives presented, including commenters' suggestions about what standards, if any, CMS should incorporate.

The following is summary of the comments we received regarding both alternatives presented, and what standards, if any, CMS should incorporate.

Comment: We received numerous comments addressing our proposal to remove the exclusion for compensation for speaking at a continuing education program. Some comments were in support to remove the exclusion stating it is an important step toward ensuring transparency. Supporting comments also agreed removing the exclusion will level the playing field with the medical education community. Numerous commenters questioned our proposal to remove the exclusion for compensation for speaking at a continuing education program. Commenters provided background regarding accrediting continuing education organizations stating that creating continuing education accreditation standards is a function of professional self-regulation and additional government regulation is not necessary.

Many commenters recommend modifying the indirect payment exclusion currently at § 403.904(i)(1) to specify a continuing education indirect payment should be excluded if the manufacturer did not know the identity of the covered recipient *before* providing the payment to a third party, such as a continuing education organization. This differs from the current indirect payment exclusion language which states the payment is excluded if the manufacturer did not know the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year. Commenters stated it is not practical for a manufacturer to not know the identity of a physician speaker receiving compensation for speaking at a continuing education event during the reporting year or by the end of the second quarter of the following reporting year because manufacturers could learn the identities of physician speakers through brochures, programs and other publications. Therefore, commenters assert that the indirect payment exclusion is not applicable to exclude compensation provided to physicians at a continuing education event and recommend the indirect

payment exclusion is modified to accommodate indirect payments provided to a physician covered recipient through a continuing medical education organization.

Additionally, commenters suggested an alternative approach where CMS would adopt established criteria, such as the Standards for Commercial Support: Standards to Ensure Independence in CME Activities, in order to have payments provided to physicians at continuing education events excluded. Similar criteria suggested by commenters to modify the exclusion were: does not pay covered speakers or attendees directly, does not select covered recipient speakers or provide a third party with a distinct, identifiable set of individuals to be considered as speakers or attendees for the continuing education program, and does not control the continuing education program content.

Response: We appreciate commenters support to remove the exclusion for compensation for speaking at a continuing education program. We appreciate the comments stating that continuing medical education accrediting organizations is a function of professional self-regulation. We believe creating consistent reporting requirements for all continuing education events, by removing the language in § 403.904(g) in its entirety, will provide enhanced regulatory clarity for stakeholders. Manufacturers reporting compensation paid to physician speakers may opt to distinguish if the payment was provided at an accredited or certified continuing education program versus an unaccredited or non-certified continuing education program by selecting the appropriate nature of payment category at § 403.904(e).

We understand commenters concern regarding learning the identity of the physician during the reporting year or by the end of the second quarter of the following reporting year. In the situation of an applicable manufacturer providing an indirect payment through a continuing education organization and learning the identity of the physician covered recipient in the allotted timeframe (during the reporting year or by the end of the second quarter of the following reporting year) the indirect payment would not meet the criteria of the indirect payment exclusion and would need to be reported. However, payments or other transfers of value, including payments made to physician covered recipients for purposes of attending or speaking at continuing education events, which do not meet the definition of an indirect payment, as

defined at § 403.902, are not reportable. For example, if an applicable manufacturer or applicable GPO provides funding to support a continuing education event but does not require, instruct, direct, or otherwise cause the continuing education event provider to provide the payment or other transfer or value in whole or in part to a covered recipient, the applicable manufacturer or applicable GPO is not required to report the payment or other transfer of value. The payment is not reportable regardless if the applicable manufacturer or applicable GPO learns the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year because the payment or other transfer of value did not meet the definition of an indirect payment. This approach is also consistent with our statement at (78 FR 9490), where we explained that “if an applicable manufacturer provided an unrestricted donation to a physician professional organization to use at the organization’s discretion, and the organization chose to use the donation to make grants to physicians, those grants would not constitute ‘indirect payments’ because the applicable manufacturer did not require, instruct, or direct the organization to use the donation for grants to physicians.” Therefore, because such payments are not indirect payments, we do not need to create an additional exclusion specific to continuing education indirect payments by modifying the indirect payment exclusion at § 403.904(i)(1).

Comment: Many commenters interpreted the removal of physician speaker compensation at continuing education events would also remove the reporting exclusion for attendees at accredited or certified continuing education events whose fees have been subsidized through the continuing medical education organization by an applicable manufacturers.

Response: We did not intend to remove the exclusion regarding subsidized fees provided to physician attendees by manufacturers at continuing education events. However, we intend for physician speaker compensation and physician attendees fees which have been subsidized through the continuing medical education organization by an applicable manufacturer to be reported unless the payment meets the indirect payment exclusion at § 403.904(i)(1). This allows for consistent reporting for physician attendees and speakers at continuing education events. We will provide sub-regulatory guidance specifying tuition

fees provided to physician attendees that have been generally subsidized at continuing education events by manufacturers are not expected to be reported. However, if a manufacturer does instruct, direct, or otherwise cause the subsidized tuition fee for a continuing education event to go to a specific physician attendee, the payment will not be excluded, since the indirect payment exclusion only applies if the manufacturer did not know the identity of the physician attendee.

Comment: Many commenters interpreted the proposed removal of § 403.904(g) to expand the exclusion to account for continuing education programs accredited or certified for nurses, optometrists, pharmacists, and others.

Response: We appreciate the comments, but the removal of § 403.904(g) was not intended to expand the exclusion. The intent is to allow for consistent reporting for compensation provided to physician speakers at all continuing education events, as well as transparency regarding compensation paid to physician speakers.

Comment: A few commenters requested CMS provide clear and realistic timeframes regarding payments related to continuing education events to allow manufacturers to provide sponsor notice as it considers proposals to eliminate the current CME exclusion.

Response: We agree with commenters that manufacturers may need additional time to comply with reporting requirements; therefore, we are finalizing data collection requirements that would begin January 1, 2016 according to this final rule for applicable manufacturers.

3. Reporting of Marketed Name (§ 403.904(c)(8))

Section 1128G(a)(1)(A)(vii) of the Act requires applicable manufacturers to report the name of the covered drug, device, biological or medical supply associated with that payment, if the payment is related to “marketing, education, or research” of a particular covered drug, device, biological, or medical supply. Section 403.904(c)(8)(i) requires applicable manufacturers to report the marketed name for each drug or biological related to a payment or other transfer of value. At § 403.904(c)(8)(ii), we require an applicable manufacturer of devices or medical supplies to report one of the following: the marketed name; product category; or therapeutic area. In the February 8, 2013, final rule, we provided applicable manufacturers with flexibility when it was determined that

the marketed name for all devices and medical supplies may not be useful for the general audience. We did not define product categories or therapeutic areas in § 403.904(c). However, since implementation of the February 8, 2013 final rule and the development of the Open Payments system, we have determined that aligning the reporting requirements for marketed name across drugs, biologics, devices and medical supplies will make the data fields consistent within the system, and also enhance consumer’s use of the data.

Accordingly, we proposed to revise § 403.904(c)(8) to require applicable manufacturers to report the marketed name for all covered drugs, devices, biologicals or medical supplies. We believe this would facilitate consistent reporting for the consumers and researchers using the data displayed publicly on the Open Payments. Manufacturers would still have the option to report product category or therapeutic area, in addition to reporting the market name, for devices and medical supplies.

Comment: We received a few comments regarding revising reporting requirements at § 403.904(c)(8). These comments mainly stated that the marketed name for a device or medical supply is not useful for the public because the public is not familiar with device or medical supply marketed names. We also received a few comments that supported requiring the reporting of marketed name for devices and medical supplies. Supporting commenters believe that reporting marketed name for all products will allow the public (including researchers and consumers) to search the data via the Open Payments public Web site for a specific device or medical supply. Commenters also stated that reporting marketed name for non-covered products is not required by the statute and therefore manufacturers should not be required to report marketed names for non-covered products. Additionally, some comments indicated reporting marketed name for devices and medical supplies for research payments is not practical because there is not a marketed name for every device or medical supply associated with research payments; rather there may only be a connection to an associated research study. A few commenters addressed that manufacturers will have an increased burden to modify reporting systems to accommodate reporting marketed name for devices and medical supplies.

Response: We appreciate the comments supporting our proposed revisions requiring reporting marketed name for devices and medical supplies.

We have finalized a modified approach to accommodate concerns regarding reporting related covered drug, device, biological or medical supply information. We agree manufacturers should not be required to report marketed names for non-covered products; therefore, we are finalizing the proposal that reporting marketed names for non-covered drugs, devices, biologicals, or medical supplies will continue to be optional. We also agree a payment or other transfer of value associated with a research payment regarding a device or medical supply may not have a marketed name. Therefore, we are finalizing the proposal that manufacturers will continue to have an option to report either a device or medical supply marketed name, therapeutic area or product category when reporting research payments.

After consideration of comments received, we agree that displaying therapeutic areas or product categories are useful for the public reviewing data on the Open Payments public Web site because the public is not familiar with marketed names for devices and medical supplies. We agree therapeutic areas and products categories are more recognizable by the public. Yet, reporting marketed names for all covered products is necessary to achieve consistent reporting and to have the ability to aggregate all payments or other transfers of value associated with a specific device or medical supply. Therefore to achieve consistent reporting by manufacturers, we will require manufacturers to report marketed name and therapeutic area or product category for all covered drugs, devices, biologicals or medical supplies. We also agree with commenters that complying with this reporting requirement will require a change in manufacturers' reporting systems; therefore, data collection for this reporting requirement would begin January 1, 2016.

4. Reporting of Stock, Stock Option, or Any Other Ownership Interest

Section 403.904(d)(3) requires the reporting of stock, stock option, or any other ownership interest. We proposed to require applicable manufacturers to report such payments as distinct categories. This will enable us to collect more specific data regarding the forms of payment made by applicable manufacturers. After issuing the February 8, 2013 final rule and the development of the Open Payments system, we determined that this specificity will increase the ease of data aggregation within the system, and also enhance consumer's use of the data. We

solicited comments on the extent to which users of this data set find this disaggregation to be useful, and whether this change presents operational or other issues on the part of applicable manufacturers.

The following is summary of the comments we received regarding the extent to which users of this data set find this disaggregation to be useful, requiring reporting of marketed name for covered devices and medical supplies, and whether this change presents operational or other issues on the part of applicable manufacturers.

Comment: Commenters agreed that requiring reporting of stock, stock option or any other ownership interest in distinct categories is useful.

Response: We agree the disaggregation of reporting stock, stock option or any other ownership interest in distinct categories. Therefore, we have finalized this provision as proposed, which requires reporting stock, stock option, or any other ownership interest form of payment or other transfer of value in distinct categories.

J. Physician Compare Web Site

1. Background and Statutory Authority

Section 10331(a)(1) of the Affordable Care Act, requires that, by no later than January 1, 2011, we develop a Physician Compare Internet Web site with information on physicians enrolled in the Medicare program under section 1866(j) of the Act, as well as information on other eligible professionals (EPs) who participate in the Physician Quality Reporting System (PQRS) under section 1848 of the Act.

CMS launched the first phase of Physician Compare on December 30, 2010 (<http://www.medicare.gov/physiciancompare>). In the initial phase, we posted the names of EPs that satisfactorily submitted quality data for the 2009 PQRS, as required by section 1848(m)(5)(G) of the Act.

Section 10331(a)(2) of the Affordable Care Act also requires that, no later than January 1, 2013, and for reporting periods that began no earlier than January 1, 2012, we implement a plan for making publicly available through Physician Compare information on physician performance that provides comparable information on quality and patient experience measures. We met this requirement in advance of January 1, 2013, as outlined below, and plan to continue addressing elements of the plan through rulemaking.

To the extent that scientifically sound measures are developed and are available, we are required to include, to

the extent practicable, the following types of measures for public reporting:

- Measures collected under the Physician Quality Reporting System (PQRS).
- An assessment of patient health outcomes and functional status of patients.
- An assessment of the continuity and coordination of care and care transitions, including episodes of care and risk-adjusted resource use.
- An assessment of efficiency.
- An assessment of patient experience and patient, caregiver, and family engagement.
- An assessment of the safety, effectiveness, and timeliness of care.
- Other information as determined appropriate by the Secretary.

As required under section 10331(b) of the Affordable Care Act, in developing and implementing the plan, we must include, to the extent practicable, the following:

- Processes to ensure that data made public are statistically valid, reliable, and accurate, including risk adjustment mechanisms used by the Secretary.
- Processes for physicians and eligible professionals whose information is being publicly reported to have a reasonable opportunity, as determined by the Secretary, to review their results before posting to Physician Compare. We have established a 30-day preview period for all measurement performance data that will allow physicians and other EPs to view their data as it will appear on the Web site in advance of publication on Physician Compare (77 FR 69166 and 78 FR 74450). Details of the preview process will be communicated directly to those with measures to preview and will also be published on the Physician Compare Initiative page (<http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/physician-compare-initiative/>) in advance of the preview period.
- Processes to ensure the data published on Physician Compare provides a robust and accurate portrayal of a physician's performance.
- Data that reflects the care provided to all patients seen by physicians, under both the Medicare program and, to the extent applicable, other payers, to the extent such information would provide a more accurate portrayal of physician performance.
- Processes to ensure appropriate attribution of care when multiple physicians and other providers are involved in the care of the patient.
- Processes to ensure timely statistical performance feedback is

provided to physicians concerning the data published on Physician Compare.

- Implementation of computer and data infrastructure and systems used to support valid, reliable and accurate reporting activities.

Section 10331(d) of the Affordable Care Act requires us to consider input from multi-stakeholder groups, consistent with sections 1890(b)(7) and 1890A of the Act, when selecting quality measures for Physician Compare. We also continue to get general input from stakeholders on Physician Compare through a variety of means, including rulemaking and different forms of stakeholder outreach (for example, Town Hall meetings, Open Door Forums, webinars, education and outreach, Technical Expert Panels, etc.). In developing the plan for making information on physician performance publicly available through Physician Compare, section 10331(e) of the Affordable Care Act requires the Secretary, as the Secretary determines appropriate, to consider the plan to transition to value-based purchasing for physicians and other practitioners that was developed under section 131(d) of the MIPPA.

Under section 10331(f) of the Affordable Care Act, we are required to submit a report to the Congress by January 1, 2015, on Physician Compare development, and include information on the efforts and plans to collect and publish data on physician quality and efficiency and on patient experience of care in support of value-based purchasing and consumer choice. Section 10331(g) of the Affordable Care Act provides that any time before that date, we may continue to expand the information made available on Physician Compare.

We believe section 10331 of the Affordable Care Act supports our overarching goals of providing consumers with quality of care information that will help them make informed decisions about their health care, while encouraging clinicians to improve the quality of care they provide to their patients. In accordance with section 10331 of the Affordable Care Act, we plan to publicly report physician performance information on Physician Compare.

2. Public Reporting of Performance and Other Data

Since the initial launch of the Web site, we have continued to build on and improve Physician Compare. On June 27, 2013, we launched a full redesign of Physician Compare bringing significant improvements including a complete overhaul of the underlying database and

a new Intelligent Search feature, addressing two of our stakeholders' primary critiques of the site—the accuracy and currency of the database and the limitations of the search function—and considerably improving Web site functionality and usability. Provider Enrollment, Chain, and Ownership System (PECOS), as the sole source of verified Medicare professional information, is the primary source of administrative information on Physician Compare. With the redesign, however, we incorporated the use of Medicare Fee-For-Service claims information to verify the information in PECOS to help ensure only the most current and accurate information is included on the site. For example, claims information is used to determine which of the active and approved practice locations in PECOS are where the professional is currently providing services. Claims information helps confirm that only the most current group practice affiliations are included on the site. Our use of claims also helps ensure that we are posting on Physician Compare the most current and accurate information available about the professionals for Medicare consumers.

We received several comments about the enhancements made to the Physician Compare Web site and the data currently on the Web site.

Comment: Several commenters noted the improvements made to the Physician Compare Web site, including the additional labeling, improvements to the “Is this you?” link, the reordering of the search results, the Intelligent Search functionality, the use of claims data to verify professionals' demographic information, denoting board certified physicians with contextual text, and explanations and disclaimers about each of the federal quality reporting programs included on the Web site. Commenters also noted an appreciation for the transparency and easy-to-use, comprehensive information available on the site to aid consumers in making informed health care decisions.

Some commenters provided suggestions for future Physician Compare enhancements. A few commenters suggested continued improvements to the Intelligent Search functionality to better find health care professionals other than physicians and additional specialty labels for Advanced Practice Registered Nurses (APRNs) and allied health professionals.

Response: We appreciate the commenters' feedback and the continued support for the Physician Compare Web site. We are committed to continuing to improve the site and its functionality to ensure it is a useful

resource for Medicare consumers, including information that can help these consumers make informed health care decisions. We also appreciate the recommendations regarding other health care professionals, and we will evaluate these recommendations for potential future inclusion. Also, we are continually working to improve and enhance the Intelligent Search functionality.

Comment: Some commenters expressed concerns about the accuracy of data such as demographic information, specialty classification, and hospital affiliation. Several commenters urged CMS to address these concerns prior to posting additional quality measure performance information on the Web site. Other commenters requested we implement a streamlined process by which professionals can confirm or correct their information in a timely manner. One commenter urged CMS to ensure that updates made in PECOS are reflected on Physician Compare within 30 days, while another commenter cautioned against using PECOS for updating information. Several commenters suggested continuing to work with stakeholders, particularly health care professionals, and/or providing educational material regarding how to keep data current to ensure the accuracy of the Web site.

Response: We appreciate the commenters' feedback regarding concerns over the accuracy of the information currently available on Physician Compare. We are committed to including accurate and up-to-date information on Physician Compare and continue to work to make improvements to the information presented.

The underlying database on Physician Compare is generated from PECOS, as well as Fee-For-Service (FFS) claims, and it is therefore critical that physicians, other health care professionals, and group practices ensure that their information is up-to-date and as complete as possible in the national PECOS database. Currently, the most immediate way to address inaccurate PECOS data on Physician Compare is by updating information via Internet-based PECOS at <https://pecos.cms.hhs.gov/pecos/login.do>. Please note that the specialties as reported on Physician Compare are those specialties reported to Medicare when a physician or other health care professional enrolls in Medicare and are limited to the specialties noted on the 855i Enrollment Form. All addresses listed on Physician Compare must be entered in and verified in PECOS.

There is a lag between when an edit is made in PECOS and when that edit is processed by the Medicare Administrative Contractor (MAC) and available in the PECOS data pulled for Physician Compare. This time is necessary for data verification but unfortunately results in a delay updating information. We are continually working to find ways to minimize this delay.

To update information not found in PECOS, such as hospital affiliation and foreign language, professionals and group practices should contact the Physician Compare support team directly at PhysicianCompare@Westat.com. Information regarding how to keep your information current can also be found on the Physician Compare Initiative page on [CMS.gov](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/physician-compare-initiative/) (<http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/physician-compare-initiative/>).

Although we appreciate the concerns raised around the PECOS data included on Physician Compare, it is necessary to continue the use of the PECOS data as it is the sole, verified source of Medicare information. However, we are aware of its limitations. For these reasons, we have instituted the use of claims information and are continuing to work to find ways to further improve the data. The data are significantly better today than they were prior to the 2013 redesign and continues to improve. We strongly encourage all professionals and group practices listed on the site to regularly check their data and to contact the support team with any questions or concerns.

Currently, Web site users can view information about approved Medicare professionals such as name, primary and secondary specialties, practice locations, group affiliations, hospital affiliations that link to the hospital's profile on Hospital Compare as available, Medicare Assignment status, education, languages spoken, and American Board of Medical Specialties (ABMS) board certification information. In addition, for group practices, users can also view group practice names, specialties, practice locations, Medicare assignment status, and affiliated professionals.

We post on the Web site the names of individual EPs who satisfactorily report under PQRS, as well as those EPs who are successful electronic prescribers under the Medicare Electronic Prescribing (eRx) Incentive Program. Physician Compare contains a link to a downloadable database of all information on Physician Compare (<https://data.medicare.gov/data/>

physician-compare), including information on this quality program participation. In addition, there is a section on each Medicare professional's profile page indicating with a green check mark the quality programs under which the EP satisfactorily or successfully reported. We proposed (79 FR 40386) to continue to include this information annually in the year following the year it is reported (for example, 2015 PQRS reporting will be included on the Web site in 2016). We did not receive any comments on this proposal. We are finalizing this proposal at this time, and therefore, will include satisfactory 2015 PQRS reporters on the Web site in 2016. The eRx Incentive Program ends in 2014 so those data will not be available in 2015 or beyond.

With the Physician Compare redesign, we added a quality programs section to each group practice profile page in order to indicate which group practices are satisfactorily reporting in the Group Practice Reporting Option (GPRO) under PQRS or are successful electronic prescribers under the eRx Incentive Program. We have also included a notation and check mark for individuals that successfully participate in the Medicare EHR Incentive Program, as authorized by section 1848(o)(3)(D) of the Act. We proposed (79 FR 40386) to continue to include this information annually in the year following the year it is reported (for example, 2015 data will be included on the Web site in 2016).

We did not receive any comments regarding our proposal regarding this PQRS GPRO. We are finalizing the proposal to include a notation for satisfactory PQRS GPRO reporters. As noted above, the eRx Incentive Program is ending in 2014, and therefore, there will not be data for this program in 2015 or beyond. We did receive comments regarding including a notation for individuals that successfully participate in the Medicare EHR Incentive Program.

Comment: Two commenters urged CMS to reconsider its decision to publicly report participation in the Medicare EHR Incentive Program due to ongoing issues related to the program—including unresolved challenges related to vendor certification delays, concerns about the relevancy to consumers, and limited ability to implement core measures. One commenter suggested including a disclaimer next to the indicator explaining these barriers and clarifying that successful participation in the EHR Incentive Program is only one of various ways to demonstrate an investment in higher quality care.

Response: We appreciate the commenters' feedback, and we will take

the suggestions provided regarding a disclaimer into consideration for possible future enhancements. We also appreciate the concerns raised about the program, specifically around vendor certification and core measures. However, despite those potential limitations, a number of professionals and groups are successfully taking part at this time and we believe it is important to continue to recognize them. Also, consumers find this information interesting and helpful. This is only one of multiple quality programs included on Physician Compare that we find important to highlight. As a result, we are going to finalize our proposal to continue including an indicator for participation in the EHR Incentive Program on the Web site.

We previously finalized a decision to publicly report the names of those EPs who report the 2014 PQRS Cardiovascular Prevention measures group in support of Million Hearts on Physician Compare in 2015, by including a check mark in the quality programs section of the profile page (78 FR 74450). We proposed (79 FR 40386) to also continue to include this information annually in the year following the year it is reported (for example, 2015 data will be included on Physician Compare in 2016).

Comment: Some commenters supported our proposal to publicly report and include an indicator for EPs who report the 2015 PQRS Cardiovascular Prevention measures group in support of Million Hearts. Commenters noted that Million Hearts is an important initiative for supporting cardiovascular health.

Response: We appreciate the commenters' support. We agree that Million Hearts is an important initiative that is improving outcomes for cardiovascular health. However, we are finalizing the removal of the Cardiovascular Prevention measure group from the PQRS program given that the two cholesterol control measures included in the measure group are no longer clinically relevant, and therefore, the measure group no longer meets the necessary threshold for PQRS of six measures and will no longer be available for reporting under the program. With the removal of the 2 cholesterol control measures, the remaining measures from the original Cardiovascular Prevention measure group are:

- Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.
- Preventive Care and Screening: Tobacco Use.

- Controlling High Blood Pressure.
- Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented.

All of these measures are available as individual measures under PQRS. Given that the Cardiovascular Prevention measure group is being eliminated from the PQRS, but that the remaining measures identified above will be available for individual reporting, we are modifying our final policy with regard to our proposal to support Million Hearts on Physician Compare. Specifically, we are finalizing that any EP that satisfactorily reports all four of the individual measures noted above will receive a green check mark indicating support for Million Hearts. A key strategy of the Million Hearts initiative is to reduce the number of heart attacks and strokes, and the program has found that reporting these quality measures is a first step toward performance improvement. We are committed to supporting this initiative, and even though the measure group is no longer available under PQRS, we think it is important to continue recognizing those individual EPs who are reporting these quality measures as individual measures. Even though the individual measures require that a potentially higher number of patients are reported on—50 percent of patients that meet the sample requirements versus just 20 patients for the measure group—we believe this does not increase burden on reporters because as currently available claims data show, significantly more EPs are already reporting these measures as individual PQRS measures versus as part of the Cardiovascular Prevention measures group. Ensuring these professionals are recognized for reporting these measures is important in ensuring we are continuing support for this important program despite the measure group no longer being available for reporting.

Finally, we will also indicate with a green check mark those individuals who have earned the 2014 PQRS Maintenance of Certification Incentive (Additional Incentive) on the Web site in 2015 (78 FR 74450).

Comment: Several commenters supported publicly reporting earners of the PQRS Maintenance of Certification (MOC) program Additional Incentive, as well as ABMS Board Certification data, while other commenters are concerned that ABMS data are not complete or only include some specialists. Multiple commenters suggested including other Boards' certifications and MOC programs, contextual certification process information, and the certifying Board's identification.

Response: We appreciate the commenters' feedback and support for including ABMS and PQRS MOC information on Physician Compare. We also understand the concerns that not all specialties are presented by the ABMS data and will review the recommendations made to include additional certification and MOC program information on the Web site for possible inclusion in the future.

We continue to implement our plan for a phased approach to public reporting performance information on Physician Compare. The first phase of this plan was finalized with the CY 2012 PFS final rule with comment period (76 FR 73419–73420), where we established that PQRS GPRO measures collected through the GPRO Web Interface for 2012 would be publicly reported on Physician Compare. The plan was expanded with the CY 2013 PFS final rule with comment period (77 FR 69166), where we established that the specific GPRO Web Interface measures that would be posted on Physician Compare would include the PQRS GPRO measures for Diabetes Mellitus (DM) and Coronary Artery Disease (CAD), and we noted that we would report composite measures for these measure groups in 2014, if technically feasible.⁶ The 2012 PQRS GPRO measures were publicly reported on Physician Compare in February 2014. Data reported in 2013 on the GPRO DM and GPRO CAD measures and composites collected via the GPRO Web Interface that meet the minimum sample size of 20 patients and prove to be statistically valid and reliable will be publicly reported on Physician Compare in December CY 2014, if technically feasible. If the minimum threshold is not met for a particular measure, or the measure is otherwise deemed not to be suitable for public reporting, the group's performance rate on that measure will not be publicly reported. We will only publish on Physician Compare those measures that are statistically valid and reliable, and therefore, most likely to help consumers make informed decisions about the Medicare professionals they choose to meet their health care needs.

Measures must be based on reliable and valid data elements to be useful to consumers and thus included on Physician Compare. A reliable data element is consistently measuring the

same thing regardless of when or where it is collected, while a valid data element is measuring what it is meant to measure. To address the reliability of performance scores, we will measure the extent to which differences in each quality measure are due to actual differences in clinician performance versus variation that arises from measurement error. Statistically, reliability depends on performance variation for a measure across clinicians ("signal"), the random variation in performance for a measure within a clinician's panel of attributed beneficiaries ("noise"), and the number of beneficiaries attributed to the clinician. High reliability for a measure suggests that comparisons of relative performance across clinicians are likely to be stable over different performance periods and that the performance of one clinician on the quality measure can confidently be distinguished from another. Potential reliability values range from zero to one, where one (highest possible reliability) means that all variation in the measure's rates is the result of variation in differences in performance, while zero (lowest possible reliability) means that all variation is a result of measurement error. Reliability testing methods included in the CMS Measures Management System Blueprint (<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MeasuresManagementSystemBlueprint.html>) include test-retest reliability and analysis of variance (ANOVA). Reliability tests endorsed by the NQF include the beta-binomial model test.

The validity of a measure refers to the ability to record or quantify what it claims to measure. To analyze validity, we can investigate the extent to which each quality measure is correlated with related, previously validated, measures. We can assess both concurrent and predictive validity. Predictive validity is most appropriate for process measures or intermediate outcome measures, in which a cause-and-effect relationship is hypothesized between the measure in question and a validated outcome measure. Therefore, the measure in question is computed first, and the validated measure is computed using data from a later period. To examine concurrent validity, the measure in question and a previously validated measure are computed using contemporaneous data. In this context, the previously validated measure should measure a health outcome related to the outcome of interest.

Comment: Many commenters supported only publishing on Physician

⁶ By "technically feasible" we mean that there are no operational constraints inhibiting us from moving forward on a given public reporting objective. Operational constraints include delays and/or issues related to data collection which render a set of quality data unavailable in the timeframe necessary for public reporting.

Compare those measures that are statistically valid and reliable. Several commenters urged CMS to carefully assess if all GPRO measure data is sufficiently reliable and valid for public reporting before posting the data. One commenter recommended removing any measures deemed unreliable or inaccurate. One commenter recommended a one-year delay in public reporting of all new measures to enable professionals to accurately report the measures and to account for measure testing and validity.

One commenter requested CMS publish the results of validity and reliability studies, as well as the methodology for choosing measures prior to posting on Physician Compare. Another commenter is concerned that measures related to patient behavior, preferences, or abilities do not provide a statistically valid portrayal of a health care professional's performance and should not be published unless the data is appropriately risk adjusted. Several other commenters also strongly urged CMS to move forward with expanding its risk adjustment methodology.

Response: We appreciate the commenters' feedback, and understand the concerns raised. As required under section 10331(b) of the Affordable Care Act, in developing and implementing the plan to include performance data on Physician Compare, we must include, to the extent practicable, processes to ensure that the data posted on the Web site are statistically valid, reliable, and accurate, including risk adjustment mechanisms used by the Secretary. We understand that this information is complex and are committed to providing data on Physician Compare that are useful to beneficiaries in assisting them in making informed health care decisions, while being accurate, valid, reliable, and complete. We will closely evaluate all quality measures under consideration for public reporting on the Web site to ensure they are meeting these standards. We will also only post data that meet the established standards of reliability and validity regardless of threshold, and regardless of measure type. Should we find a measure meeting the minimum threshold to be invalid or unreliable for any reason, the measure will not be reported. We are also making changes in light of the concerns about first year measures. We will not publicly post measures that are in their first year given the concerns raised about their validity, reliability, accuracy, and comparability. After a measure's first year in the program, CMS will evaluate the measure to see if and when the measure is suitable for public reporting.

Also, we will continue to analyze the measure data to ensure that risk adjustment concerns are taken into consideration. All data are analyzed and reviewed by our Technical Expert Panel (TEP). A summary of the TEP recommendations is made public on the Physician Compare Initiative page (<http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/physician-compare-initiative/Informational-Materials.html>) when available.

In the November 2011 Medicare Shared Savings Program final rule (76 FR 67948), we noted that because Accountable Care Organization (ACO) providers/suppliers that are EPs are considered to be a group practice for purposes of qualifying for a PQRS incentive under the Shared Savings Program, we would publicly report ACO performance on quality measures on Physician Compare in the same way as we report performance on quality measures for PQRS GPRO group practices. Public reporting of performance on these measures is presented at the ACO level only. The first sub-set of ACO measures was also published on the Web site in February 2014. ACO measures can be viewed by following the link for Accountable Care Organization (ACO) Quality Data on the homepage of the Physician Compare Web site (<http://medicare.gov/physiciancompare/aco/search.html>).

As part of our public reporting plan for Physician Compare, in the CY 2013 PFS final rule with comment period (77 FR 69166 and 69167), we also finalized the decision to publicly report Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS) data for group practices of 100 or more eligible professionals reporting data in 2013 under the GPRO and for ACOs participating in the Shared Savings Program, if technically feasible. We anticipate posting these data on Physician Compare in late 2014, if available.

We continued to expand our plan for public reporting data on Physician Compare in the CY 2014 PFS final rule with comment period (78 FR 74449). In that final rule we finalized a decision that all measures collected through the GPRO Web Interface for groups of two or more EPs participating in 2014 under the PQRS GPRO and for ACOs participating in the Medicare Shared Savings Program would be available for public reporting in CY 2015. As with all measures we finalized with regard to Physician Compare, these data would include measure performance rates for measures reported that meet the minimum sample size of 20 patients and

prove to be statistically valid and reliable. We also finalized a 30-day preview period prior to publication of quality data on Physician Compare. This will allow group practices to view their data as it will appear on Physician Compare before it is publicly reported. We decided that we will detail the process for the 30-day preview and provide a detailed timeline and instructions for preview in advance of the start of the preview period. ACOs will be able to view their quality data that will be publicly reported on Physician Compare through the ACO Quality Reports, which will be made available to ACOs for review at least 30 days prior to the start of public reporting on Physician Compare.

We also finalized a decision to publicly report in CY 2015 on Physician Compare performance on certain measures that group practices report via registries and EHRs in 2014 for the PQRS GPRO (78 FR 74451). Specifically, we finalized making available for public reporting performance on 16 registry measures and 13 EHR measures (78 FR 74451). These measures are consistent with the measures available for public reporting via the Web Interface. We will indicate the mechanism by which these data were collected and only those data deemed statistically comparable, valid, and reliable would be published on the site.

We also finalized publicly reporting patient experience survey-based measures from the CG-CAHPS measures for groups of 100 or more eligible professionals who participate in PQRS GPRO, regardless of GPRO submission method, and for Shared Savings Program ACOs reporting through the GPRO Web Interface or other CMS-approved tool or interface (78 FR 74452). For 2014 data, we finalized publicly reporting data for the 12 summary survey measures also finalized for groups of 25 to 99 for PQRS reporting requirements (78 FR 74452). These summary survey measures would be available for public reporting group practices of 100 or more EPs participating in PQRS GPRO, as well as group practices of 25 to 99 EPs when collected via any certified CAHPS vendor regardless of PQRS participation, as technically feasible. For ACOs participating in the Shared Savings Program, the patient experience measures that are included in the Patient/Caregiver Experience domain of the Quality Performance Standard under the Shared Savings Program (78 FR 74452) will be available for public reporting in 2015.

For 2014, we also finalized publicly reporting 2014 PQRS measure data

reported by individual EPs in late CY 2015 for individual PQRS quality measures specifically identified in the final rule with comment period, if technically feasible. Specifically, we finalized to make available for public reporting 20 individual measures collected through a registry, EHR, or

claims (78 FR 74453–74454). These are measures that are in line with those measures reported by groups via the GPRO Web Interface.

Finally, in support of the HHS-wide Million Hearts Initiative, we finalized a decision to publicly report, no earlier than CY 2015, performance rates on

measures in the PQRS Cardiovascular Prevention measures group at the individual EP level for data collected in 2014 for the PQRS (78 FR 74454). See Table 48 for a summary of our final policies for public reporting data on Physician Compare.

TABLE 48: Summary of Previously Finalized Policies for Public Reporting on Physician Compare

Data Collection Year	Public Reporting Year	Reporting Mechanism(s)	Quality Measures and Data for Public Reporting
2012	2013	Web Interface (WI), EHR, Registry, Claims	Include an indicator for satisfactory reporters under PQRS successful e-prescribers under eRx, and participants in the EHR Incentive Program.
2012	2014	WI	5 Diabetes Mellitus (DM) and Coronary Artery Disease (CAD) measures collected via the WI for group practices reporting under PQRS GPRO with a minimum sample size of 25 patients and Shared Savings Program ACOs.
2013	2014	WI, EHR, Registry, Claims	Include an indicator for satisfactory reporters under PQRS, successful e-prescribers under eRx, and participants in the EHR Incentive Program. Include an indicator for EPs who earn a PQRS Maintenance of Certification Incentive and EPs who report the PQRS Cardiovascular Prevention measures group in support of Million Hearts.
2013	Expected to be December 2014	WI	Up to 6 DM and 2 CAD measures collected via the GPRO WI for groups of 25 or more EPs and Shared Savings Program ACOs with a minimum sample size of 20 patients. Will include composites for DM and CAD, if feasible.
2013	Expected to be December 2014	WI	Up to 5 CG-CAHPS summary measures for groups of 100 or more EPs reporting under PQRS GPRO via the WI and up to 6 ACO CAHPS summary measures for Shared Savings Program ACOs.
2014	Expected to be 2015	WI, EHR, Registry, Claims	Include an indicator for satisfactory reporters under PQRS and participants in the EHR Incentive Program. Include an indicator for EPs who earn a PQRS Maintenance of Certification Incentive and EPs who report the PQRS Cardiovascular Prevention measures group in support of Million Hearts.
2014	Expected to be late 2015	WI, EHR, Registry, Administrative Claims	All measures reported via the GPRO WI, 13 EHR, and 16 Registry GPRO measures are also available for group practices of 2 or more EPs reporting under PQRS GPRO with a minimum sample size of 20 patients. Also, all Shared Savings Program ACO measures are available for public reporting. Include composites for DM and CAD, if feasible.
2014	Expected to be late 2015	WI, Certified Survey Vendor	Up to 12 CG-CAHPS summary measures for groups of 100 or more EPs reporting via the WI and group practices of 25 to 99 EPs reporting via a CMS-approved certified survey vendor, as well as 6 ACO CAHPS summary measures for Shared Savings Program ACOs reporting through the GPRO Web Interface or other CMS-approved tool or interface.
2014	Expected to be late 2015	Registry, EHR, or Claims	A sub-set of 20 PQRS measures submitted by individual EPs that align with those available for group reporting via the WI and that are collected through a Registry, EHR, or claims with a minimum sample size of 20 patients.
2014	Expected to be late 2015	Registry	Measures from the Cardiovascular Prevention measures group reported by individual EPs in support of the Million Hearts Initiative with a minimum sample size of 20 patients.

3. Final Policies for Public Data Disclosure on Physician Compare in 2015 and 2016

We are continuing the expansion of public reporting on Physician Compare by making an even broader set of quality measures available for publication on the Web site. We started the phased approach with a small number of possible PQRS GPRO Web Interface measures for 2012 and have been steadily building on this to provide Medicare consumers with more information to help them make informed health care decisions. As a result, we proposed (79 FR 40388) to increase the measures available for public reporting in the CY 2015 proposed PFS rule.

Comment: Although multiple commenters supported continuing the phased approach to public reporting of quality data, a number of commenters are concerned with the aggressive timeline for publicly reporting performance data. Several commenters supported a more gradual approach to public reporting to evaluate the public response to data prior to widespread implementation, ensure accuracy, and present data in a format that is easy to understand, meaningful, and actionable for both patients and health care professionals. A few commenters were unsure if CMS conducted analysis of consumer use of the site and urged CMS to do so. Other commenters opposed the extensive expansion until existing Web site problems are addressed.

Response: We appreciate the commenters' feedback, and we appreciate the concerns raised. However, we believe that public reporting of quality data has been a measured, phased approach which started with the publication of just five 2012 PQRS GPRO measures collected via the Web Interface for 66 group practices and 141 ACOs (76 FR 73417) and continues with a similarly limited set of 2013 PQRS GPRO Web Interface measures (77 FR 69166). We started to build on this plan with the 2014 Physician Fee Schedule (PFS) final rule (78 FR 74446). This rule made additional PQRS GPRO measures available for public reporting, including a subset of measures reported via Registry and EHR, as well as a sub-set of 20 individual EP PQRS measures. Therefore, the proposals put forth this year are just the next step in the process to realize goals for authorization of Physician Compare. We are confident that taking this phased approach has afforded us the opportunity to prepare for this significant expansion.

Throughout this process, we have been engaging with consumers and stakeholders and regularly testing the site and the information to be included to ensure it is accurately presented and understood. We are also continually working to improve the Web site and the administrative and demographic information included. We continue to encourage physicians, other health care professionals, and group practices to ensure their information is updated in PECOS so that we can ensure the most accurate information is available on Physician Compare. We also encourage individuals and groups to reach out to the Physician Compare support team at PhysicianCompare@Westat.com for any questions or concerns regarding the information included on the Web site.

We proposed (79 FR 40388) to expand public reporting of group-level measures by making all 2015 PQRS GPRO measure sets across group reporting mechanisms—GPRO Web Interface, registry, and EHR—available for public reporting on Physician Compare in CY 2016 for groups of 2 or more EPs, as appropriate by reporting mechanism.⁷ Similarly, we also proposed that all measures reported by Shared Savings Program ACOs would be available for public reporting on Physician Compare. As with all quality measures proposed for inclusion on Physician Compare, we noted that only measures that prove to be valid, reliable, and accurate upon analysis and review at the conclusion of data collection would be included on the Web site.

Comment: Commenters were both positive and negative in regard to our proposal to expand the group-level measures available for public reporting to all measures reported under 2015 PQRS GPRO. Commenters in support of the proposal noted group-level measures are a robust indication of care team quality and helpful to consumers. Some commenters opposed the expansion and cited concerns with the accuracy of current data as well as measure fidelity. One commenter encouraged CMS to ensure that GPRO quality data is accurately labeled and accessible through the group entry only to ensure it is clear what the quality measure represents. One commenter asked for clarification on the availability of the PQRS GPRO Web Interface reporting option for groups of two or more EPs.

Response: We appreciate the commenters' feedback on our proposal

to report all 2015 PQRS measures reported via the Web Interface, EHR, and Registry for group practices of 2 or more EPs participating in the PQRS GPRO. As noted, Physician Compare will only publicly report those measures evaluated to be comparable, reliable, and valid. Also, we will continue to work to ensure that measures are labeled accurately and accompanied by explanations that are both true to the measure specifications and accurately understood by health care consumers, while adhering to HHS plain language guidelines. Measure data accuracy is of paramount importance to CMS. The measure data currently available on Physician Compare was previewed by those group practices that currently have 2012 PQRS GPRO data available on Physician Compare prior to publication with no concerns raised regarding accuracy. Since being published, no group practices with GPRO data have raised concerns regarding the accuracy of the measure data available. To confirm, the Web Interface reporting option will remain limited to groups of 25 or more EPs. Smaller groups, groups of 2 to 24 EPs, can report under the PQRS via EHR or Registry. We also clarify that group-level data is only published at the group level—included on the group practice profile page—on Physician Compare. And, in response to comments that raised concern about measures reported in the first year, we have decided that we will not publicly report a measure that is in its first year. By first year we mean a measure that is newly available for reporting under PQRS.

We also received comments specifically about EHR measures.

Comment: Commenters were opposed to publicly reporting EHR measures, citing that it is too soon to publicly post performance data from eCQMs without additional work to verify the validity and accuracy of the measure results. One commenter suggested that new quality measures could be piloted by health care professionals prior to requiring their use within a federal program. One commenter strongly encouraged developing a tutorial that allows the public to better understand this data.

Response: We appreciate the commenters' feedback regarding including measures collected via EHRs. Group practices will have the ability to report measures via an EHR prior the 2015 data collection. Therefore, this reporting mechanism will not be in its first year of use at this time. As a result, we do not believe it is too soon to report these quality measures. As noted, only comparable, valid, reliable, and accurate

⁷ Tables Q1–Q27 detail proposed changes to available PQRS measures. Additional information on PQRS measures can be found on the CMS.gov PQRS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html>.

data will be included on Physician Compare. All measures slated for public reporting will be consumer tested to ensure they are accurately understood prior to publication. If concerns surface from this testing, we will evaluate if the requirements for public reporting are not suitably met and if the measure or measures in question should be suppressed and not publicly reported to ensure only those measures that are valid, reliable, and accurate and inform quality choice are included on the site.

Given the value of these group-level data, and the successful publication of such data to date, we are finalizing our proposal to report all 2015 PQRS measures for all reporting options for group practices of 2 or more EPs participating in PQRS GPRO, and all 2015 measures reported by ACOs. Consistent with this final policy, we are making a conforming change to the regulation at § 425.308(e) to provide that all quality measures reported by ACOs will be reported on Physician Compare in the same way as for group practices that report under the PQRS.

We also proposed (79 FR 40389) that measures must meet the public reporting criteria of a minimum sample size of 20 patients.

Comment: Several commenters supported the proposed minimum sample size of 20 patients. However, the majority of commenters believed a patient threshold of 20 is too low to be statistically valid, which commenters claim may result in inaccurate quality scores based on one outlier. Commenters recommended CMS use a higher threshold to ensure validity. Several commenters also urged CMS to test measures and composites with 20 patients and to provide an opportunity for public comment and to review reliability and validity.

Response: We appreciate the commenters' feedback and understand the concerns raised regarding the 20 patient minimum sample size. However, we believe this threshold of 20 patients is a large enough sample to protect patient privacy for reporting on the Web site, and aligns with the reliability threshold previously finalized for the Value-Based Modifier (VM) (77 FR 69166). As we continue to work to align quality initiatives and minimize reporting burden on physicians and other health care professionals, we are finalizing a patient sample size of 20 patients.

We proposed to include an indicator of which reporting mechanism was used and to only include on the site measures

deemed statistically comparable.⁸ We received several comments regarding data comparability, generally.

Comment: Some commenters expressed concern with the comparability of measures reported through different reporting mechanisms and requested notation specifying the measure differences. One commenter supported only publicly reporting measures with specifications consistent across all reporting mechanisms, while another commenter recommended that CMS group results by the data collection methodology to improve comparability.

Response: Though we understand concerns regarding including measures collected via different mechanisms, CMS is conducting analyses to ensure that these measures align across different reporting mechanisms. This analysis is done on a measure per measure basis. For example, if a measure is reported via claims, then the measure specifications would be aligned with a measure being reported via EHR as long as it stays consistent with the original measure intent. Only those measures that are proven to be comparable and most suitable for public reporting will be included on Physician Compare and made publicly available. Therefore, we are finalizing our proposal to report data from the available reporting mechanisms and to include a notation indicating which reporting mechanism was used.

We proposed (79 FR 40389) to publicly report all measures submitted and reviewed and found to be statistically valid and reliable in the Physician Compare downloadable file. However, we proposed that not all of these measures necessarily would be included on the Physician Compare profile pages. As we noted, consumer testing has shown profile pages with too much information and/or measures that are not well understood by consumers can negatively impact a consumer's ability to make informed decisions. Our analysis of the collected measure data, along with consumer testing and stakeholder feedback, will determine specifically which measures are published on profile pages on the Web site. Statistical analyses will ensure the measures included are statistically valid and reliable and comparable across data collection mechanisms. Stakeholder feedback will ensure all measures meet current clinical standards. CMS will continue to reach out to stakeholders in the professional community, such as

⁸ By statistically comparable, CMS means that the quality measures are analyzed and proven to measure the same phenomena in the same way regardless of the mechanism through which they were collected.

specialty societies, to ensure that the measures under consideration for public reporting remain clinically relevant and accurate. When measures are finalized significantly in advance of moment they are collected, it is possible that clinical guidelines can change rendering a measure no longer relevant. Publishing that measure can lead to consumer confusion regarding what best practices their health care professional should be subscribing to.

As we noted in the proposed rule (79 FR 40389), the primary goal of Physician Compare is to help consumers make informed health care decisions. If a consumer does not properly interpret a quality measure and thus misunderstands what the quality score represents, the consumer cannot use this information to make an informed decision. Through concept testing, CMS will test with consumers how well they understand each measure under consideration for public reporting. If a measure is not consistently understood and/or if consumers do not understand the relevance of the measure to their health care decision making process, CMS will not include the measure on the Physician Compare profile page as inclusion will not aid informed decision making. Finally, consumer testing will help ensure the measures included on the profile pages are accurately understood and relevant to consumers, thus helping them make informed decisions. This will be done to ensure that the information included on Physician Compare is consumer friendly and consumer focused.

Comment: Several commenters supported the proposal to have all 2015 measures available for download with only a select group of measures on the Web site. One commenter further emphasized CMS should create consistent formatting with Hospital Compare downloadable files.

Response: We appreciate the commenters' feedback and support for this proposal. We are finalizing the proposal to include all measures in a downloadable file and limiting the measures available on Physician Compare profile pages to those measures that not only meet the requirements of public reporting such as validity, reliability, accuracy, and comparability, but that also are accurately understood and interpreted by consumers as evidenced via consumer testing. This will ensure that the measures presented on Physician Compare help them make informed health care decisions without overwhelming them with too much information. We will also take into future consideration the

recommendation regarding the Hospital Compare file.

We also received comments regarding stakeholder involvement and consumer testing.

Comment: Commenters encouraged continued involvement of measure developers and stakeholders in the public reporting development process. Several commenters appreciated the continued collaboration with specialty societies via town hall meetings and other mechanisms. Several commenters advocated for more transparency by providing the opportunity for the public to comment on the deliberations of the Physician Compare TEP; regular engagement with interested stakeholders; and increased communication about the measure consideration process, including methods and interpretation of performance. Some commenters appreciated that CMS will continue to reach out to stakeholders in the professional community to ensure that the measures under consideration for public reporting remain clinically relevant and accurate. One commenter suggested an opportunity for stakeholder associations to participate in the 30-day measure preview process.

Response: We appreciate the commenters' feedback regarding stakeholder outreach and involvement in Physician Compare. As we noted, section 10331(d) of the Affordable Care Act requires that the Secretary take into consideration input provided by multi-stakeholder groups, consistent with sections 1890(b)(7) and 1890A of the Act, as added by section 3014 of the Act, in selecting quality measures for use on Physician Compare. We also are dedicated to providing opportunities for stakeholders to provide input. We will continue to identify the best ways to accomplish this. We will also review all recommendations provided for future consideration.

Comment: Many commenters supported consumer testing to ensure only meaningful measures are included on the site. One commenter suggested CMS first focus on communicating validated and meaningful information in a user-friendly way. One commenter urged CMS to consult a broader array of stakeholders during concept testing, while another commenter specified the inclusion of health care professionals. Some commenters requested that CMS share with professional associations or measure developers any information obtained through consumer concept testing. A few commenters asked for more details on concept testing plans, while another recommended CMS use concept testing for the information

currently on the Physician Compare. One commenter emphasized testing must occur prior to placing these additional measures on the Web site in late 2016. One commenter believed health care professionals must be aware of what measures will be reported to the Physician Compare Web site before the reporting period begins.

Response: We appreciate the commenters' feedback. We will continue to conduct consumer testing in terms of both usability testing—to ensure the site is easy to navigate and functioning appropriately—and concept testing—to ensure users understand the information included on the Web site and that information included resonates with health care consumers. We are continually working to test the information planned for public reporting with consumers. We regularly test the information currently on the Web site with site users. We are planning concept testing of the measures being finalized in this rule prior to publication in 2016 and we will work to ensure that valid, reliable, and meaningful information is included on the Web site. This testing ensures that the best information is shared and that it is shared in a way that is correctly interpreted.

We will also engage stakeholders for feedback, including input from the public, consumers, and health care professionals, as appropriate and feasible through such opportunities as Town Halls, Listening Sessions, Open Door Forums, and Webinars. We will review feedback for future consideration. Although we establish in rulemaking the subset of measures available for posting on the Physician Compare Web site, at this time, however, it is not possible for us to provide stakeholders with the exact list of measures that will be included on the Web site prior to our analysis of the reported data to know which measures meet the criteria we specified previously for public reporting.

As is the case for all measures published on Physician Compare, group practices will be given a 30-day preview period to view their measures as they will appear on Physician Compare prior to the measures being published. As in previous years, we will detail the process for the 30-day preview and provide a detailed timeline and instructions for preview in advance of the start of the preview period. ACOs will be able to view their quality data that will be publicly reported on Physician Compare through the ACO Quality Reports, which will be made available to ACOs for review at least 30

days prior to the start of public reporting on Physician Compare.

Comment: Several commenters were in support of the 30-day preview period prior to publication of quality data. Many commenters urged CMS to also allow group practices, ACOs, and EPs the opportunity to correct and/or appeal any errors found in the performance information before it is posted on the Web site. Several commenters recommended CMS postpone posting information if a group practice or EP files an appeal and flags their demographic data or quality information as problematic. Other commenters noted that a 30-day preview period is insufficient and requested that CMS extend the period to 60 or 90 days. One commenter believed the preview period should match the PQRS committee's measure review timeline of 9 months. Some commenters sought clarification on how CMS plans to notify EPs of the preview period and requested more detail about correcting errors found during the preview period.

Response: We appreciate the commenters' feedback regarding the 30-day preview period for quality measures on Physician Compare. Detailed instructions regarding how to preview measure data, the time frame for the measure preview, and directions for how to address any concerns or get additional help during this process is shared at the start of the preview period with all groups and individuals that have data to preview. If an error is found in the measure display during this 30-day preview, the directions explain how to contact the Physician Compare team by both phone and email to have concerns addressed. Errors will be corrected prior to publication. If measure data has been collected and the measure has been deemed suitable for public reporting, the data will be published. This 30-day period is in line with the preview period provided for other public reporting programs such as Hospital Compare. To date, our experience with this preview period for group practices demonstrates that 30 days is sufficient time to allow for preview to be conducted. It is important that quality data be shared with the public as soon as possible so it is as current and relevant as possible when published. To avoid further delaying this publication we will maintain the 30-day preview period.

Group practices and EPs with available data for public reporting will be informed via email when the preview period is going to take place. Group practices and EPs will be provided instructions for previewing data and information for on how to request help

or have questions answered.

Additionally, information regarding the preview period will be included on the Physician Compare Initiative page on CMS.gov. As noted, ACOs will preview their data via their ACO Quality Reports, which will be sent at least 30 days before data are publicly reported. There is no preview period for demographic data. These data are currently publicly available. If a group practice or EP has questions about their demographic data, they should contact the Physician Compare support team at PhysicianCompare@Westat.com.

In addition to making all 2015 PQRS GPRO measures available for public reporting, we solicited comment (78 FR 40389) on creating composites using 2015 data and publishing composite scores in 2016 by grouping measures based on the PQRS GPRO measure groups, if technically feasible. We indicated we would analyze the data collected in 2015 and conduct psychometric and statistical analyses, looking at how the measures best fit together and how accurately they are measuring the composite concept, to create composites for certain PQRS GPRO measure groups, including but not limited to:

- Care Coordination/Patient Safety (CARE) Measures
- Coronary Artery Disease (CAD) Disease Module
- Diabetes Mellitus (DM) Disease Module

- Preventive (PREV) Care Measures

In particular, we would analyze the component measures that make up each of these measure groups to see if a statistically viable composite can be constructed with the data reported for 2015. Composite scores have proven to be beneficial in providing consumers a better way to understand quality measure data, as composites provide a more concise, easy to understand picture of physician quality.

Comment: Commenters were both positive and negative in regard to our request for information on publicly reporting composite scores. Some commenters stated composites should only be publicly reported if statistically reliable, risk adjusted, or medically meaningful, and should be scientifically or consumer tested prior to public display. A few commenters also suggested NQF endorsement of individual components and composites before finalizing any composites. Several commenters strongly urged CMS to seek input from relevant specialty societies, measure developers, consumers, and other stakeholders on the construction and display of the composites. A few commenters opposed

public reporting of composites, but suggested providing physicians the composite scores confidentially through the QRURs. Several commenters noted concerns about the proposal to create composites given the variability in the methodologies, difficulty validating the results, and use of stand-alone measures developed to be reported individually. One commenter suggested stand-alone measures are preferable to composites in relatively small and heterogeneous measure sets. A few commenters suggested posting additional information about composite measures on Physician Compare clarifying that composite groups are not readily available at this time for all measure groups. One commenter urged CMS to retain more comprehensive information about the measures within each composite measure in the downloadable file. One commenter does not specifically support the Oncology Composite Score on Physician Compare.

Response: We appreciate the commenters' feedback on this request for information. We will be carefully reviewing all concerns raised and recommendations made as we continue to evaluate options for including composites in future rulemaking. This concept was put forth merely to seek comment and no formal proposal was made, so we are not finalizing any decisions regarding composite scores at this time. However, given that we received feedback from stakeholders indicating such composite scores are desired, we plan to analyze the data once it is collected to establish the best possible composite, which would help consumers use these quality data to make informed health care decisions, and will consider proposing such composites in future rulemaking.

Similar to composite scores, benchmarks are also important to ensuring that the quality data published on Physician Compare are accurately interpreted and appropriately understood. A benchmark will allow consumers to more easily evaluate the information published by providing a point of comparison between groups. We continue to receive requests from all stakeholders, but especially consumers, to add this information to Physician Compare. As a result, we proposed (79 FR 40389) to publicly report on Physician Compare in 2016 benchmarks for 2015 PQRS GPRO data using the same methodology currently used under the Shared Savings Program. This ACO benchmark methodology was previously finalized in the November 2011 Shared Savings Program final rule (76 FR 67898), as amended in the CY 2014 PFS final rule with comment period (78 FR

74759). Details on this methodology can be found on CMS.gov at <http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/MSSP-QM-Benchmarks.pdf>. We proposed to follow this methodology using the 2014 PQRS GPRO data.

We proposed to calculate benchmarks using data at the group practice TIN level for all EPs who have at least 20 cases in the denominator. A benchmark per this methodology is the performance rate a group practice must achieve to earn the corresponding quality points for each measure. Benchmarks would be established for each percentile, starting with the 30th percentile (corresponding to the minimum attainment level) and ending with the 90th percentile (corresponding to the maximum attainment level). A quality scoring point system would then be determined. Quality scoring would be based on the group practice's actual level of performance on each measure. A group practice would earn quality points on a sliding scale based on level of performance: performance below the minimum attainment level (the 30th percentile) for a measure would receive zero points for that measure; performance at or above the 90th percentile of the performance benchmark would earn the maximum points available for the measure. The total points earned for measures in each measure group would be summed and divided by the total points available for that measure group to produce an overall measure group score of the percentage of points earned versus points available. The percentage score for each measure group would be averaged together to generate a final overall quality score for each group practice. The goal of including such benchmarks would be to help consumers see how each group practice performs on each measure, measure group, and overall in relation to other group practices.

Comment: Many commenters supported the use of benchmarks to help consumers make informed health care decisions. However, several commenters did not support the calculation of an overall quality score, as they believe it will result in the unfair comparison of all group practices. Additional commenters noted that benchmarks using percentiles will be difficult for consumers to understand and encouraged consumer testing to remedy this problem. Some commenters noted appropriate methodology is needed when potential data constraints impact the calculation of benchmarks. Several commenters also asked for

clarification on the impact of exception rates on quality scores and how benchmarks will be displayed, noting the risk of arbitrary thresholds potentially exaggerating minor performance differences. A commenter asked for the opportunity to review sample data prior to supporting the proposed methodology, while another noted that benchmarks need to be set prior to the beginning of the new measurement period. One commenter sought clarification on whether the benchmarking methodology would be the same as the methodology applied under the Value-Modifier. Several commenters urged CMS to use consistent benchmarking across its programs to promote consistency and minimize confusion. One commenter cautioned the use of benchmarks, noting it can lead to an incomplete and potentially misleading indicator of quality.

Response: We appreciate the commenters' feedback on our proposal to include on Physician Compare a benchmark for 2015 PQRS GPRO measures (and measures reported by individual EPs) measures based on the current Shared Savings Program benchmark methodology. Although we agree benchmarks can add great value for consumers, we understand the many concerns raised. As a result, we have made a decision not to finalize this proposal at this time. We want to be sure to discuss more thoroughly potential benchmarking methodologies with our stakeholders prior to finalizing the proposal. We also want to evaluate other programs' methodologies, including the Value Modifier, to work toward better alignment across programs. We therefore feel it would be best to forgo finalizing a methodology at this time in favor of a stronger, potentially better aligned methodology that can be included in future rulemaking.

Understanding the value consumers place on patient experience data and the commitment to reporting these data on Physician Compare, we proposed (79 FR 40390) publicly reporting in CY 2016 patient experience data from 2015 for all group practices of two or more EPs, who meet the specified sample size requirements and collect data via a CMS-specified certified CAHPS vendor. The patient experience data available are specifically the CAHPS for PQRS and CAHPS for ACO measures, which include the CG-CAHPS core measures. For group practices, we proposed to make available for public reporting these 12 summary survey measures:

- Getting Timely Care, Appointments, and Information.

- How Well Providers Communicate.
- Patient's Rating of Provider.
- Access to Specialists.
- Health Promotion & Education.
- Shared Decision Making.
- Health Status/Functional Status.
- Courteous and Helpful Office Staff.
- Care Coordination.
- Between Visit Communication.
- Helping You to Take Medication as Directed.

• Stewardship of Patient Resources. We proposed that these 12 summary survey measures would be available for public reporting for all group practices. For ACOs participating in the Shared Savings Program, we proposed (79 FR 40390) that the patient experience measures that are included in the Patient/Caregiver Experience domain of the Quality Performance Standard under the Shared Savings Program in 2015 would be available for public reporting in 2016. We would review all quality measures after they are collected to ensure that only those measures deemed valid and reliable are included on the Web site.

We received a number of comments around our proposals to include CAHPS measures on Physician Compare.

Comment: Several commenters supported our proposal to publicly report CAHPS for PQRS data for all group practices that have met the minimum sample size requirements and collect the data using a certified CMS-approved vendor. One commenter strongly encouraged CMS to make public reporting on patient experience measures mandatory for groups of all sizes and individual EPs. However, a few commenters were concerned with public reporting of CAHPS or other patient experience survey data due to the subjectivity of the surveys or the cost of administering the surveys.

Response: We appreciate the commenters' feedback. At this time reporting of CAHPS measures for PQRS is only available at the group practice level, so we will continue to consider these data for group practices. We understand the concerns raised regarding subjectivity and cost. However, we are confident that CAHPS is a well-tested collection mechanism that produces valid and comparable measures of physician quality based on the extensive testing and work that has been done by the Agency for Healthcare Research and Quality's (AHRQ) and specifically the CAHPS Consortium (for more information visit <https://cahps.ahrq.gov/>). This work illustrates that these measures are accurate measures of patient experience. Because CAHPS for PQRS can be one part of a group's participation in PQRS and are

data greatly desired by consumers, we also believe concerns regarding cost are outweighed. For these reasons, we are finalizing our proposal to make available for public reporting the 12 summary survey CAHPS measures outlined in this rule on Physician Compare for group practices and ACOs, as appropriate.

Comment: Commenters were generally supportive of the proposal to publicly report 12 summary CAHPS scores; however, some are concerned that several CAHPS summary survey measures cannot accurately capture aspects of care over which an individual physician does not have direct control, such as "Getting Timely Care, Appointments and Information" and "Access to Specialists," and urged CMS to only report these measures on an aggregate, group level. Another commenter is concerned with "Stewardship of Patient Resources" survey measure, noting that it is not a physician's role to manage a patient's pocketbook and that other barriers, apart from costs, can impede access to care.

One commenter supported the creation of benchmarks for CAHPS for PQRS measures, and suggested CMS clarify whether those benchmarks will be the same as the ACO CAHPS measure benchmarks, or whether the benchmarks will be specific to the PQRS program, but calculated using the same methodology.

Response: The CAHPS for PQRS measures are designed to be group-level measures. These data will not be calculated for individual EPs; they will be evaluated at the group practice level. We do appreciate the commenters' feedback regarding concerns over specific measures. One important consideration is that because the CAHPS measures are group-level, they are not attributing aspects of care to an individual EP, as not all aspects of care can be easily attributed to a single professional. Prior to deciding the specific measures that will be publicly reported on Physician Compare, we will ensure the measures meet the reliability and validity requirements set for public reporting and that the measures are understood and accurately interpreted by consumers. If a summary survey measure does not meet these criteria, it will not be publicly reported on Physician Compare. At this time, we are not adopting any benchmarks for CAHPS for PQRS on Physician Compare.

Comment: One commenter sought additional information on how CAHPS for PQRS performance measures will be displayed. Another commenter suggested that public reporting of

CAHPS for PQRS utilize the Hospital Compare model by displaying aggregate scores for measures with a footnote or click-through option to view the performance data.

Response: We appreciate the commenters' feedback regarding display of CAHPS for PQRS measures. We generally make decisions about measure display after consumer testing and stakeholder outreach, so we will take these recommendations into consideration.

We previously finalized in the 2014 PFS final rule with comment period (78 FR 74454) that 20 measures in the 2014 PQRS measures for individual EPs collected via registry, EHR, or claims would be available for public reporting in late 2015, if technically feasible. We proposed (79 FR 40390) to expand on this in two ways. First, we proposed to publicly report these same 20 measures for 2013 PQRS data in early 2015. We stated that publicly reporting these 2013 individual measures would help ensure individual level measures are made available as soon as possible. We believe that consumers are looking for measures about individual doctors and other health care professionals, and this would make these quality data available to the public sooner.

Comment: One commenter supported our proposal to publicly report 20 individual EP-level 2013 PQRS measures in early 2015, while another commenter opposed the proposal noting that physicians were unaware at the time of data collection that these performance rates would be published. Concerns were raised that timelines needed to be finalized before the public reporting period had ended.

Response: We appreciate the commenters' feedback and understand concerns that the 2013 individual EP PQRS data were submitted without an explicit understanding that these data would be made public. As a result, we are not finalizing this proposal.

Second, we proposed (79 FR 40390) to make all individual EP-level PQRS measures collected via registry, EHR, or claims available for public reporting on Physician Compare for data collected in 2015 to be publicly reported in late CY 2016, if technically feasible.⁹ We stated that this would provide the opportunity for more EPs to have measures included on Physician Compare, and it would provide more information to consumers to make informed decisions about their

health care. As with group-level measures, we proposed to publicly report all measures submitted and reviewed and deemed valid and reliable in the Physician Compare downloadable file. However, not all of these measures necessarily would be included on the Physician Compare profile pages. Our analysis of the reported measure data, along with consumer testing and stakeholder feedback, would determine specifically which measures are published on profile pages on the Web site. In this way, quality information on individual practitioners would be available, as has been regularly requested by Medicare consumers, without overwhelming consumers with too much information.

Comment: Some commenters supported expanding public reporting of individual-level quality measures to all 2015 PQRS measures collected through a Registry, EHR, or claims, noting consumers are looking for individual doctors so this information is helpful. Several commenters opposed making 2015 PQRS individual EP measures available for public reporting in 2016 and are concerned that individual quality measurement is technically challenging to validate and may be difficult for consumers to understand. Another commenter suggested it is too much information for consumers. One commenter stated that data reported through different reporting mechanisms is not comparable so this proposal should not be finalized. One commenter believed that the relatively small numbers of patients seen by individual physicians raises questions about the ability to truly differentiate quality. Several commenters supported group practice level public reporting as an alternative to individual public reporting.

Response: We appreciate the commenters' feedback and agree with those comments that support individual-level measure data should be posted on the site as soon as technically feasible. We also strongly agree with commenters that these data will help health care consumers make informed decisions about the care they receive. However, we appreciate the concerns raised by other commenters' in opposition to posting individual EP measures. We are committed to including only the most accurate, statistically reliable, and valid quality of care measure data on Physician Compare. We will also ensure that only those data that are evaluated to be comparable will be publicly reported understanding the concerns regarding data collected via different reporting mechanisms.

We will continue to test the PQRS measures with consumers to ensure the measures are presented and described in a way that is accurately understood. We will only include on the Web site those measures that resonate with consumers to ensure they are not overwhelmed with too much information. Regarding concerns around the number of patients seen, only those measures that are reported for the accepted sample size of 20 patients will be publicly reported. Because of the overwhelming consumer demand for individual EP data and the value these data provide to patients, we are finalizing our proposal to publicly report all 2015 individual EP PQRS measures collected through a Registry, EHR, or claims, except for those measure that are new to PQRS and thus in their first year.

As noted above for group-level reporting, composite scores and benchmarks are critical in helping consumers best understand the quality measure information presented. For that reason, in addition to making all 2015 PQRS measures available for public reporting, we sought comment (79 FR 40390) to create composites and publish composite scores by grouping measures based on the PQRS measure groups, if technically feasible. We indicated that we would analyze the data collected in 2015 and conduct psychometric and statistical analyses to create composites for PQRS measure groups to be published in 2016, including:

- Coronary Artery Disease (CAD) (see Table 30)
- Diabetes Mellitus (DM) (see Table 32)
- General Surgery (see Table 33)
- Oncology (see Table 38)
- Preventive Care (see Table 41)
- Rheumatoid Arthritis (RA) (see Table 42)
- Total Knee Replacement (TKR) (see Table 45)

We would analyze the component measures that make up each of these measure groups to see if a statistically viable composite can be constructed with the data reported for 2015. As noted for group practices, we believe that providing composite scores will give consumers the tools needed to most accurately interpret the quality data published on Physician Compare. We would analyze the component measures that make up each of these measure groups to see if a statistically viable composite can be constructed with the data reported for 2015.

As noted above, we received multiple comments about creating composites at both the group practice and individual EP-level. Those comments are addressed above. Since we were only seeking

⁹Tables Q1–Q27 detail proposed changes to available PQRS measures. Additional information on PQRS measures can be found on the CMS.gov PQRS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html>.

comments on possible future composites, we are not finalizing any at this time, but we will take those comments into consideration for the future.

In addition, we proposed (79 FR 40390) to use the same methodology outlined above for group practices to develop benchmarks for individual practitioners. We believe that providing benchmarks will give consumers the tools needed to most accurately interpret the quality data published on Physician Compare. As discussed above, we received comments on the proposed benchmarking methodology for both group practices and individual EPs. Those comments were previously addressed. As noted, we are not finalizing this proposed benchmarking methodology at this time.

Previously, we indicated an interest in including specialty society measures on Physician Compare. In the proposed rule, we solicited comment (79 FR 40390) on posting these measures on the Web site. We also solicited comment on the option of linking from Physician Compare to specialty society Web sites that publish non-PQRS measures. Including specialty society measures on the site or linking to specific specialty society measures would provide the opportunity for more eligible professionals to have measures included on Physician Compare and thus help Medicare consumers make more informed choices. The quality measures developed by specialty societies that would be considered for future posting on Physician Compare are those that have been comprehensively vetted and tested and are trusted by the physician community. These measures would provide access to available specialty specific quality measures that are often highly regarded and trusted by the stakeholder community and, most importantly, by the specialties they represent. We indicated that we were working to identify possible societies to reach out to, and solicited comment on the concept, as well as potential specific society measures of interest.

Comment: Many commenters supported specialty society measures on Physician Compare or linking to specialty society Web sites that publish non-PQRS measures. Several commenters specified that the specialty society measures should be supported by scientific evidence, developed by relevant clinical experts, and adequately vetted. Some commenters suggested a disclaimer specifying, along with the measure description, the limitations of PQRS or clarification that CMS is not endorsing and has not validated specialty society measures. One

commenter supported specialty measures as long as data is open sourced, provided at no cost, and made available to all. One commenter suggested also including links to additional patient-friendly educational materials on specialty societies' Web sites.

Several commenters opposed posting non-PQRS data or linking to non-governmental, privately managed Web sites. One commenter stated CMS should maintain control over the public disclosure process to reduce potential for variable data. One commenter is concerned that the approach will lead to more confusion for consumers and added burden for physicians, and another commenter cautioned CMS to ensure measures that are meaningful to consumers and comparable to those reported upon under the PQRS. A few commenters sought additional information on this process if this becomes a formal proposal in future years.

Response: We appreciate commenters' feedback on our request for information. We were only seeking comment at this time. We will consider feedback, recommendations made, and concerns raised, and may consider addressing specialty society measures and Web site links on Physician Compare in future rulemaking.

Finally, we proposed (79 FR 40390) to make available on Physician Compare, 2015 Qualified Clinical Data Registry (QCDR) measure data collected at the individual level or aggregated to a higher level of the QCDR's choosing—such as the group practice level, if technically feasible. QCDRs are able to collect both PQRS measures and non-PQRS measures.¹⁰ We believe that making QCDR data available on Physician Compare further supports the expansion of quality measure data available for EPs and group practices regardless of specialty therefore providing more quality data to consumers to help them make informed decisions. Per the proposal, the QCDR would be required to declare during their self-nomination if they plan to post data on their own Web site and allow Physician Compare to link to it or if they will provide data to CMS for public reporting on Physician Compare. We proposed that measures collected via QCDRs must also meet the established public reporting criteria, including a 20 patient minimum sample size. As with PQRS data, we proposed to publicly

report in the Physician Compare downloadable file all measures submitted, reviewed, and deemed valid and reliable. However, not all of these measures necessarily would be included on the Physician Compare profile pages. Our analysis of the reported measure data, along with consumer testing and stakeholder feedback would determine specifically which measures are published on profile pages on the Web site.

Comment: We received many comments on publicly reporting 2015 QCDR measure data. Some commenters supported publicly reporting QCDR data to provide specialty-specific quality information for patients. One commenter proposed CMS consumer test QCDR measures to ensure valid sampling, consistent methods, and comparable results across specialties.

A number of commenters did not support the proposal, however. Most notably, commenters believed that public reporting first year data for new measures would be problematic. Other commenters opposed publicly reporting QCDR data until accurate benchmarking data can be developed, or professionals have the opportunity to analyze the data and make improvements. Several commenters requested NQF endorsement for all QCDR measures, and one commenter suggested that CMS develop rules and guidelines for measure stewards who develop non-PQRS measures housed in QCDR's. One commenter stated society-sponsored non-PQRS measures need to be subjected to the same reliability, validity, and consumer testing that CMS promises for other information on Physician Compare. Another commenter noted that QCDR measures are collected for quality improvement purposes and have not been vetted for public reporting.

Response: We appreciate the commenters' feedback on our proposal to include all 2015 QCDR data at the individual level or aggregated to a higher level of the QCDR's choosing. We understand the many concerns raised. We specifically appreciate the concerns that the QCDR non-PQRS measures be held to the same standards as the PQRS measures in terms of reliability, validity, and accuracy, and that these measures be adequately tested and vetted for public reporting. Understanding these concerns, we will review all data prior to public reporting to ensure that the measures included meet the same standards as the PQRS measures being publicly reported. As with the PQRS measures being made available for public reporting, if the QCDR measures do not meet the requirements for public

¹⁰ http://www.cms.gov/apps/ama/license.asp?file=/PQRS/downloads/2014_PQRS_IndClaimsRegistry_MeasureSpecs_SupportingDocs_12132013.zip

reporting we have set out, the measures will not be publicly reported. Regarding the comment that QCDR data should not be publicly reported until accurate benchmarks are available, we appreciate this concern but are moving forward with the proposal because we believe that even without benchmarks, these data can provide consumers with very valuable and instructive information as is the case, and thus consistent, with the PQRS measures we are finalizing for publication without a benchmark. We do feel it is important to include QCDR data in our public reporting plan, as some commenters agreed, because using QCDR data can ultimately provide an opportunity to have measures available for public reporting for a greater number of health care professionals covering more specialties, providing more and more useful information to health care consumers. We are therefore finalizing our proposal to publicly report QCDR measures with some modifications.

We agree that it may be problematic to publicly report first year measures. Health care professionals should be afforded the opportunity to simply learn from the first year data, and not have this information shared publicly until the measure can be vetted for accuracy. As a result, we will not publicly report any QCDR measures newly available for reporting for at least one year. This is consistent with the VM policy regarding first year measures and addresses a significant number of the concerns raised, which were specifically in regard to not including first year measures for public reporting. If first year measures are not publicly reported this will provide us the necessary time to review and vet the QCDR measures to ensure that only those truly suitable for public reporting are posted on Physician Compare when they mature.

Comment: A number of commenters considered the proposed timeline for publicly reporting 2015 QCDR measure data too aggressive to ensure that data will be valid and reliable and in a format which consumers can understand; some suggested delaying or

implementing a gradual approach. A few commenters were concerned public reporting so soon will damage start up efforts of new registries.

Several commenters supported the proposal only if the QCDR measures are posted on Physician Compare. One commenter believed this will streamline the public reporting process. One commenter noted that QCDRs Web sites are not intended for public consumption and would require new infrastructure, while another commenter was concerned with a potential conflict of interest by linking to nongovernmental Web sites. Two commenters support linking to the QCDR Web sites to view the data to reduce consumer confusion. Another commenter urged consistent and uniform public reporting.

Response: We appreciate the commenters' feedback and do acknowledge the concerns regarding the timeline. To mitigate some of these concerns, we are adopting some refinements to what we proposed, such as not reporting first year measures. We believe that not publicly reporting measures on Physician Compare that are not ready for public reporting will help QCDRs early in their development and not reflect negatively on the new QCDR. We are also finalizing a decision to publish QCDR 2015 data on the Physician Compare Web site in 2016. However, as finalized in the PQRS section of this rule, we are not requiring these data to be publicly reported on the QCDR Web sites in order to address concerns that there is not enough time for QCDRs to establish user-friendly Web sites for sharing data as well as concerns about data consistency. Publicly reporting the QCDR data on Physician Compare also provides a uniform public reporting approach, eliminates the need for health care professionals to verify their data in multiple locations, and provides one, user-friendly Web site for consumers trying to locate quality data. After this first year of public reporting QCDR data, we will evaluate if maintaining this policy is most desirable.

Comment: A few commenters supported reporting individual or data aggregating to a higher level, but the majority recommend QCDR measure data only be reported on Physician Compare at the group practice level. One commenter suggested requiring the individual level data to be made publicly available, so long as results are valid and reliable. One commenter believed QCDRs should have the option to publicly disclose performance data by physician specialty within a group, in addition to at the individual or group levels.

Response: We appreciate the commenters' feedback. As stated above, only those data that are deemed valid, reliable, and accurate will be publicly reported on Physician Compare. This will be true for all QCDR data as well. Given that we will publish QCDR data on Physician Compare, but not first year measures, this will enable us to review and vet the QCDR measures prior to public reporting in 2016. In this way, we can ensure only the most appropriate available QCDR measures are publicly reported, and that they are reported in a way that will help consumers make informed decisions.

QCDR data will only be publicly reported at the individual-EP level. We appreciate the commenters' concerns and support for group-level data. However, QCDR data is not necessarily aggregated to a level consistent with how PQRS defines a group practice. Therefore, aggregated data cannot be accommodated on Physician Compare at this time. And, under PQRS, only individual EPs can report via a QCDR. Therefore, only including individual-level QCDR data on Physician Compare is consistent with the PQRS program's implementation of the data. As with all data included on Physician Compare, only data deemed valid, reliable, and accurate will be publicly reported on the Web site.

Table 49 summarizes the Physician Compare proposals we are finalizing for with regard to 2015 data.

TABLE 49—SUMMARY OF FINALIZED DATA FOR PUBLIC REPORTING

Data collection year	Publication year	Data type	Reporting mechanism	Finalized proposals regarding quality measures and data for public reporting
2015	2016	PQRS, PQRS GPRO, EHR, and Million Hearts.	Web Interface, EHR, Registry, Claims.	Include an indicator for satisfactory reporters under PQRS, participants in the EHR Incentive Program, and EPs who satisfactorily report the individual PQRS Cardiovascular Prevention measures in support of Million Hearts.
2015	2016	PQRS GPRO & ACO GPRO.	Web Interface, EHR, Registry, and Administrative Claims.	All 2015 PQRS GPRO measures reported via the Web Interface, EHR, and Registry that are available for public reporting for group practices of 2 or more EPs and all measures reported by ACOs with a minimum sample size of 20 patients.

TABLE 49—SUMMARY OF FINALIZED DATA FOR PUBLIC REPORTING—Continued

Data collection year	Publication year	Data type	Reporting mechanism	Finalized proposals regarding quality measures and data for public reporting
2015	2016	CAHPS for PQRS& CAHPS for ACOs.	CMS-Specified Certified CAHPS Vendor.	2015 CAHPS for PQRS for groups of 2 or more EPs and CAHPS for ACOs for those who meet the specified sample size requirements and collect data via a CMS-specified certified CAHPS vendor.
2015	2016	PQRS	Registry, EHR, or Claims.	All 2015 PQRS measures for individual EPs collected through a Registry, EHR, or claims.
2015	2016	QCDR data	QCDR	All individual-EP level 2015 QCDR data.

4. Additional Comments Received Beyond the Scope of This Rulemaking

We received comments regarding the availability of measures at the individual and group-levels for certain types of specialties and for other health care professionals, but that were beyond the scope of this rule. We have summarized and addressed those comments below.

Comment: Several commenters are concerned about the availability of specialty-specific and non-physician measures available for public reporting due to the proposed removal of PQRS measures and/or limitations of measures reported via claims or the Web Interface. Two commenters noted that some specialty specific measures are not suitable for public reporting, as the data is not meaningful to consumers. Commenters also noted that the absence of measure data on Physician Compare due to limited available or meaningful measures may mislead consumers. Commenters requested disclaimers be added or additional education be conducted to explain that there could be the absence of measure data due to measure limitations and not poor quality. Several commenters expressed concern with publicly reporting any data until measure limitations can be analyzed or addressed. Two commenters supported the continued work of CMS with professional societies to address measure concerns.

Response: We appreciate the commenters' feedback. We understand that availability of PQRS measures may make it difficult for some specialties to report. We hope that the introduction of additional measures, such as QCDR measures and patient experience measures, will help mitigate concerns regarding quality data availability in the short term. And, it is important to realize that as most searches on Physician Compare are specialty based, if there are not measures for a given specialty, users will not be evaluating some physicians or non-physicians with measures and some without within that specialty. That can also work to mitigate

these concerns. Finally, we also understand that disclaimers and other types of explanatory language are necessary to help inform health care consumers as they use the Web site. We will continue to work to ensure that the language included on Physician Compare addresses the concerns raised and helps users understand that there are a number of reasons a physician or other health care professional may not have quality data on the Web site.

Comment: We received comments on how quality measures are displayed on Physician Compare. Several commenters opposed star rankings or similar systems and are concerned that disparate quality scores will result in inappropriate distinctions of quality for physicians whose performance scores are not statistically different. One commenter suggested increased efforts to establish the best method for presenting performance information to consumers and to educate consumers on the meaning of performance differences.

Response: At the time this rule is finalized, Physician Compare does not employ a ranking system—the site does not provide a system that determines that one professional is better than other professionals based on any set of defined criteria. Performance scores are displayed visually using five stars as a pictographic representation of the percent. In this way, each star represents 20 percentage points. The performance rate is also displayed as a percent. Consumer testing has shown that this display is most accurately understood and interpreted by Web site users. Stakeholders were provided opportunities to view alternate display options and this display was also supported by a majority of those who took part in review sessions prior to the initial publication of measure data. That said, we intend to continue to work with consumers and stakeholders to find the best way to display data that will best serve consumers and most accurately represent the data.

Comment: Several commenters are concerned with the use of physician-

centric language in the proposed rule and on Physician Compare, noting that the name of the site could be more inclusive of all eligible health care professionals. One commenter suggested providing information throughout the Web site about the full array of qualified professionals. One commenter requested the definition of the Clinical Nurse Specialist change, while another specified changes for Registered Dietitian/Nutrition Professionals. One commenter asked CMS to assure that audiologists are meaningfully represented and can be easily identified by other professionals and patients. One commenter recommended that the enrollment application process also be refined to provide a provider neutral enrollment process.

Response: We appreciate the commenters' feedback, and will take all recommendations into consideration for the future. The site was named consistent with section 10331 of the Affordable Care Act. Throughout the site we note that both physicians and other health care professionals are available to search and view. If a professional is in approved status in PECOS and has submitted Medicare Fee-For-Service claims in their name in the last 12 months, they will be included on Physician Compare. We are always working to ensure the plain language definitions of the various types of professionals included on the site are accurate and up-to-date. We will review the recommendations made around this information and work with relevant stakeholders to update as appropriate.

Comment: Commenters provided suggestions for additional information to publicly report on Physician Compare, including participation in a quality improvement registry for certain services, fellowship status, other voluntary quality improvement initiatives, educational materials about a disease or procedure, specialist-specific training and certification data, and other qualifications, such as the Certified Medical Director designation and the Certificate of Added Qualifications in

Geriatric Medicine. One commenter supported inclusion of information about physician compliance with Medicare rules. Another commenter suggested including measures related to cancer care.

Response: We appreciate the commenters' feedback and recommendations for including additional information on the Web site. We will review all recommendations provided and evaluate the feasibility for potential inclusion in the future. One important consideration around many of these recommendations is whether there is a readily available national-level data source. With this in mind, the recommendations will be closely evaluated.

Comment: Several commenters noted the limitations of CAHPS for PQRS measures for some health care professionals and supported adding other types of patient experience data to Physician Compare, including the Surgical CAHPS® and experience data collected via other sources. One commenter suggested publicly reporting beneficiary satisfaction information in addition to CAHPS for PQRS measures. Another commenter suggested reporting patient experience data for primary care physicians and clinical quality performance for specialists.

Response: We appreciate the commenters' feedback. We agree that Surgical CAHPS® data is useful to consumers and we are exploring how we can incorporate this information into Physician Compare.

Comment: One commenter encouraged CMS to recognize improvements by individual professionals and groups over time, while another noted the benefits of cross-sectional and cross-time comparisons.

Response: We appreciate the commenters' feedback and the recommendation to consider longitudinal as well as other comparisons. We will evaluate these recommendations as we move forward with Physician Compare.

Comment: One commenter suggested that the measures being removed from PQRS due to 100 percent performance be added to the Physician Compare Web site as display measures believing that these topped out measures would add value to Physician Compare.

Response: We appreciate the commenter's feedback. However, if the measure data are no longer going to be reported in PQRS, these data will not be available to consider for posting on Physician Compare.

Comment: One commenter urged CMS to create mechanisms to attribute

Medicare Advantage quality data to physician groups for display on Physician Compare and enable CG–CAHPS vendors to include beneficiaries enrolled in MA, as well as in traditional Medicare fee-for-service.

Response: We appreciate the commenters' suggestions and will evaluate the feasibility of these recommendations for the future.

5. Report to Congress

Section 10331(f) of the Affordable Care Act, requires that no later than January 1, 2015, we submit a report to Congress on the Physician Compare Web site that includes information on the efforts of and plans made by the Secretary of Health and Human Services to collect and publish data on physician quality and efficiency and on patient experience of care in support of consumer choice and value-based purchasing. We anticipate timely submission of this report, including discussion about the phase-in of the Web site and developments to date. The report will also address the expansion of data on the Web site, in regard to section 10331(g) of the Affordable Care Act, and future plans for the Web site.

K. Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System

This section contains the requirements for the Physician Quality Reporting System (PQRS). The PQRS, as set forth in sections 1848(a), (k), and (m) of the Act, is a quality reporting program that provides incentive payments (ending with 2014) and payment adjustments (beginning in 2015) to eligible professionals and group practices based on whether they satisfactorily report data on quality measures for covered professional services furnished during a specified reporting period or to individual eligible professionals that satisfactorily participate in a qualified clinical data registry (QCDR).

The requirements in this rule primarily focus on the 2017 PQRS payment adjustment, which will be based on an eligible professional's or a group practice's reporting of quality measures data during the 12-month calendar year reporting period occurring in 2015 (that is, January 1 through December 31, 2015). Please note that, during the comment period, we received comments that were not related to our specific proposals for the requirements for the 2017 PQRS payment adjustment in the CY 2015 PFS proposed rule. While we appreciate the commenters' feedback, these comments will not be specifically addressed in this CY 2015

PFS final rule with comment period, as they are beyond the scope of this rule. However, we will consider these comments when developing policies and program requirements for future years. Please note that we continue to focus on aligning our requirements with other quality reporting programs, such as the Medicare EHR Incentive Program for Eligible Professionals, the VM, and the Medicare Shared Savings Program, where and to the extent appropriate and feasible.

The PQRS regulations are located at § 414.90. The program requirements for the 2007 through 2014 PQRS incentives and the 2015 and 2016 PQRS payment adjustment that were previously established, as well as information on the PQRS, including related laws and established requirements, are available at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html>. In addition, the 2012 PQRS and eRx Experience Report, which provides information about eligible professional participation in PQRS, is available for download at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2012-PQRS-and-eRx-Experience-Report.zip>.

We note that eligible professionals in critical access hospitals billing under Method II (CAH–IIs) were previously not able to participate in the PQRS. Due to a change we made in the manner in which Medicare reimburses eligible professionals in CAH–IIs, it is feasible for eligible professionals in CAH–IIs to participate in the PQRS for reporting beginning in 2014. Although eligible professionals in CAH–IIs are not able to use the claims-based reporting mechanism to report PQRS quality measures data in 2014, beginning in 2015, these eligible professionals in CAH–IIs may participate in the PQRS using ALL reporting mechanisms available, including the claims-based reporting mechanism. Finally, please note that in accordance with section 1848(a)(8) of the Act, all eligible professionals who do not meet the criteria for satisfactory reporting or satisfactory participation for the 2017 PQRS payment adjustment will be subject to the 2017 PQRS payment adjustment with no exceptions.

In addition, in the CY 2013 PFS final rule with comment period, we introduced the reporting of the Agency for Healthcare Research and Quality's (AHRQ's) Clinician & Group (CG) Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey measures, referenced at <https://cahps.ahrq.gov/Surveys-Guidance/CG/>

[index.html](#). AHRQ's CAHPS Clinician & Group Survey Version 2.0 (CG-CAHPS) includes 34 core CG-CAHPS survey questions. In addition to these 34 core questions, the CAHPS survey measures that are used in the PQRS include supplemental questions from CAHPS Patient-Centered Medical Home Survey, Core CAHPS Health Plan Survey Version 5.0, other CAHPS supplemental items, and some additional questions. Since the CAHPS survey used in the PQRS covers more than just the 34 core CG-CAHPS survey measures, we will refer to the CG-CAHPS survey measures used in the PQRS as "CAHPS for PQRS." We proposed to make this revision throughout § 414.90. We did not receive comments on referring to the CG-CAHPS survey measures as reported in the PQRS as CAHPS for PQRS, and are therefore finalizing this proposal as proposed.

1. Requirements for the PQRS Reporting Mechanisms

The PQRS includes the following reporting mechanisms: claims; qualified registry; EHR (including direct EHR products and EHR data submission vendor products); the Group Practice Reporting Option (GPRO) web interface; certified survey vendors, for the CAHPS for PQRS survey measures; and the QCDR. Under the existing PQRS regulation, § 414.90(h) through (k) govern which reporting mechanisms are available for use by individuals and group practices for the PQRS incentive and payment adjustment. This section III.K.1 contains our proposals to change the qualified registry, direct EHR and EHR data submission vendor products, QCDR, and GPRO web interface reporting mechanisms, as well as public comments and our final decisions on those proposals. Please note that we did not propose to make changes to the claims-based reporting mechanism.

Please note that, in the CY 2015 PFS proposed rule, we solicited comments on whether, in future years, we should allow for more frequent submissions, such as quarterly or year-round submissions, for PQRS quality measures data submitted via the qualified registry, EHR, QCDR, and GPRO web interface reporting mechanisms (79 FR 40392, 40393, and 40395 respectively). Many commenters supported this concept, as it would provide vendors and their products greater flexibility in data submission. However, some of these commenters who expressed support for more frequent submissions of data preferred that the ability to provide more frequent submission of data be optional, not mandatory. We appreciate the commenters' support for this

concept and will consider the commenters' feedback if and when we propose this policy in future rulemaking.

a. Changes to the Requirements for the Qualified Registry

In the CY 2013 and 2014 PFS final rules with comment period, we established certain requirements for entities to become qualified registries for the purpose of verifying that a qualified registry is prepared to submit data on PQRS quality measures for the reporting period in which the qualified registry seeks to be qualified (77 FR 69179 through 69180 and 78 FR 74456). Specifically, in the CY 2014 PFS final rule with comment period, in accordance with the satisfactory reporting criterion we finalized for individual eligible professionals or group practices reporting PQRS quality measures via qualified registry, we finalized the following requirement that a qualified registry must be able to collect all needed data elements and transmit to CMS the data at the TIN/NPI level for at least 9 measures covering at least 3 of the National Quality Strategy (NQS) domains (78 FR 74456).

As we explain in further detail in this section III.K, we proposed that—in addition to requiring that an eligible professional or group practice report on at least 9 measures covering 3 NQS domains—an eligible professional or group practice who sees at least 1 Medicare patient in a face-to-face encounter, as we define that term in section III.K.2.a., and wishes to meet the criterion for satisfactory reporting of PQRS quality measures via a qualified registry for the 2017 PQRS payment adjustment would be required to report on at least 2 cross-cutting PQRS measures specified in Table 52. In accordance with this proposal, we proposed to require that, in addition to being required to be able to collect all needed data elements and transmit to CMS the data at the TIN/NPI level for at least 9 measures covering at least 3 of the NQS domains for which a qualified registry transmits data, a qualified registry would be required to be able to collect all needed data elements and transmit to CMS the data at the TIN/NPI level for ALL cross-cutting measures specified in Table 52 for which the registry's participating eligible professionals are able to report.

Comment: Some commenters opposed this proposed requirement, stating that this requirement seems overly burdensome. The commenters noted that, in some instances, certain registries report PQRS quality measures data for certain specialties for which the

proposed cross-cutting measure set does not apply. Commenters also requested exceptions to this requirement for "closed registries," which the commenter defined as registries not open to all eligible professionals for participation.

Response: We understand the commenters' concerns regarding requiring registries to be able to report on all cross-cutting measures specified in Table 52. We made this proposal to allow eligible professionals and group practices the option to report on as many cross-cutting measures as are applicable. However, we understand that it may be overly burdensome for certain registries, such as those registries geared towards specialties for which the cross-cutting measures do not apply or "closed registries." Therefore, based on the comments received, we are not finalizing our proposal to require that qualified registries be able to report on all cross-cutting measures specified in Table 52 for which the registry's participating eligible professionals are able to report. We note, however, as we describe in greater detail below, eligible professionals and group practices using the registry-based reporting mechanism that see at least 1 Medicare patient in a face-to-face encounter must still report on 1 cross-cutting measure to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment. Therefore, in order for the registry's participating eligible professionals and group practices to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment, the registry must be able to report to report on at least 1 cross-cutting measure on behalf of its participating eligible professionals and group practices.

Furthermore, in the CY 2013 PFS final rule, we noted that qualified registries have until the last Friday of February following the applicable reporting period (for example, February 28, 2014, for reporting periods ending in 2013) to submit quality measures data on behalf of its eligible professionals (77 FR 69182). We continue to receive stakeholder feedback, particularly from qualified registries currently participating in the PQRS, urging us to extend this submission deadline due to the time it takes for these qualified registries to collect and analyze the quality measures data received after the end of the reporting period. Although, at the time, we emphasized the need to have quality measures data received by CMS no later than the last Friday of the February occurring after the end of the applicable reporting period, we believe it is now feasible to extend this deadline. Therefore, we proposed to

extend the deadline for qualified registries to submit quality measures data, including, but not limited to, calculations and results, to March 31 following the end of the applicable reporting period (for example, March 31, 2016, for reporting periods ending in 2015). We invited and received the following public comments on this proposal:

Comment: Commenters supported this proposal, as it would allow qualified registries an additional month to submit quality measures data.

Response: We appreciate the commenters' positive feedback. Based on the comments received and for the reasons stated in the proposed rule, we are finalizing our proposal to extend the deadline for qualified registries to submit quality measures data, including, but not limited to, calculations and results, to March 31 following the end of the applicable reporting period (for example, March 31, 2016, for reporting periods ending in 2015).

b. Changes to the Requirements for the Direct EHR and EHR Data Submission Vendor Products That Are CEHRT

In the CY 2013 PFS final rule with comment period, we finalized requirements that although EHR vendors and their products would no longer be required to undergo the previously existing qualification process, we would only accept the data if the data are: (1) Transmitted in a CMS-approved XML format utilizing a Clinical Document Architecture (CDA) standard such as Quality Reporting Data Architecture (QRDA) level 1 (and for EHR data submission vendor products that intend to report for purposes of the proposed PQRS-Medicare EHR Incentive Program Pilot, if the aggregate data are transmitted in a CMS-approved XML format); and (2) in compliance with a CMS-specified secure method for data submission (77 FR 69183 through 69187). To further clarify, EHR vendors and their products must be able to submit data in the form and manner specified by CMS. Accordingly, direct EHRs and EHR data submission vendors must comply with CMS Implementation Guides for both the QRDA-I and QRDA-III data file formats. The Implementation Guides for 2014 are available at http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/Guide_QRDA_2014eCQM.pdf. Updated guides for 2015, when available, will be posted on the CMS EHR Incentive Program Web site at <http://www.cms.gov/Regulations-and-Guidance/Legislation/>

EHRIncentivePrograms. These implementation guides further describe the technical requirements for data submission to ensure the data elements required for measure calculation and verification are provided. We proposed to continue applying these requirements to direct EHR products and EHR data submission vendor products for 2015 and beyond. We received no public comment on our proposal to continue applying these requirements. Therefore, we are finalizing our proposal to have direct EHRs and EHR data submission vendors comply with CMS Implementation Guides for both the QRDA-I and QRDA-III data file formats for 2015 and beyond.

For 2015 and beyond, we also proposed to have the eligible professional or group practice provide the CMS EHR Certification Number of the product used by the eligible professional or group practice for direct EHRs and EHR data submission vendors. We believe this requirement is necessary to ensure that the eligible professionals and group practices that are using EHR technology are using a product that is certified EHR technology (CEHRT) and will allow CMS to ensure that the eligible professional or group practice's data is derived from a product that is CEHRT. We solicited but received no public comment on this proposal. However, we do not believe it is feasible for us to collect this information at this time, because we do not have a venue in which to store this information. Therefore, we are not finalizing this proposal.

c. Changes to the Requirements for the QCDR

Reporting Outcome Measures:

In accordance with the criterion for satisfactory participation in a QCDR that we proposed for the 2017 PQRS payment adjustment, we proposed to require a QCDR to possess at least 3 outcome measures (or, in lieu of 3 outcome measures, at least 2 outcome measures and at least 1 of the following other types of measures—resource use, patient experience of care, or efficiency/appropriate use) (79 FR 40393). We solicited and received the following comment on this proposal:

Comment: The majority of commenters opposed this proposal. The commenters believed this proposed requirement was overly burdensome, particularly for the QCDRs that do not have 3 outcome measures available for reporting currently. The commenters urged CMS not to bring about change to a reporting option that is still relatively new.

Response: We understand the commenters' concerns. As we describe in greater detail in section III.K.3.a. below, we are modifying our final criterion for satisfactory participation in a QCDR for the 2017 PQRS payment adjustment by only requiring that an eligible professional report on at least 2 outcome measures (or, in lieu of 2 outcome measures, at least 1 outcome measure and 1 of the following other types of measures—resource use, patient experience of care, efficiency/appropriate use, or safety). Since this proposal was intended to be consistent with our final criterion for the satisfactory participation in a QCDR for the 2017 PQRS payment adjustment, we are modifying this proposal and finalizing the following requirement for QCDRs: A QCDR must possess at least 2 outcome measures. If the QCDR does not possess 2 outcome measures, then, in lieu of 2 outcome measures, the QCDR must possess at least 1 outcome measure and 1 of the following other types of measures—resource use, patient experience of care, efficiency/appropriate use, or safety. We believe this modification does not significantly change the current QCDR requirement to possess at least 1 outcome measure, as a QCDR may still possess only one measure for reporting in 2015 and still qualify to become or remain a QCDR provided that the QCDR possesses 1 of the following other types of measures—resource use, patient experience of care, efficiency/appropriate use, or safety.

Reporting Non-PQRS Measures:

To establish the minimum number of measures (9 measures covering at least 3 NQS domains) a QCDR may report for the PQRS, we placed a limit on the number of non-PQRS measures (20) that a QCDR may submit on behalf of an eligible professional at this time (78 FR 74476). We proposed to change this limit from 20 measures to 30 (79 FR 40393). We solicited and received the following public comment on this proposal:

Comment: Some commenters supported this proposal, as it would allow QCDRs to report on more measures that may cover a broader range of specialties and sub-specialties. A few commenters opposed this proposal, as the commenters urged CMS not to bring about change to a reporting option that is still relatively new.

Response: We appreciate the commenters' positive feedback. While we understand the need to provide continuity and stability in this reporting option, particularly during its early stages, we believe that the benefits of allowing QCDRs potentially to cover a broader range of specialties and sub-

specialties outweigh the commenters' concerns. Therefore, we are finalizing our proposal that beginning with the criteria for satisfactory participation for the 2017 PQRS payment adjustment, a QCDR may submit quality measures data for a maximum of 30 non-PQRS measures. Please note that this limit does not apply to measures contained in the PQRS measure set, as QCDRs can report on as many measures in the PQRS measure set as they wish. Also, please note that QCDRs are not required to report on 30 non-PQRS measures. Rather, the reporting of non-PQRS measures is optional, and our final rule here increases the number of optional additional measures that a QCDR may elect to submit.

Definition of a Non-PQRS Measure:

Additionally, CMS' experience during the 2014 self-nomination process shed light on clarifications needed on what is considered a non-PQRS measure. Therefore, to clarify the definition of non-PQRS measures, we proposed the following parameters for a measure to be considered a non-PQRS measure:

- A measure that is not contained in the PQRS measure set for the applicable reporting period.
- A measure that may be in the PQRS measure set but has substantive differences in the manner it is reported by the QCDR. For example, PQRS measure 319 is reportable only via the GPRO Web interface. A QCDR wishes to report this measure on behalf of its eligible professionals. However, as CMS has only extracted the data collected from this quality measure using the GPRO Web interface, in which CMS utilizes a claims-based assignment and sampling methodology to inform the groups on which patients they are to report, the reporting of this measure would require changes to the way that the measure is calculated and reported to CMS via a QCDR instead of through the GPRO Web interface. Therefore, due to the substantive changes needed to report this measure via a QCDR, PQRS measure 319 would be considered a non-PQRS measure. In addition, CAHPS for PQRS is currently reportable only via a CMS-certified survey vendor. However, although CAHPS for PQRS is technically contained in the PQRS measure set, we consider the changes that will need to be made to be available for reporting by individual eligible professionals (and not as a part of a group practice) significant enough as to treat CAHPS for PQRS as a non-PQRS measure for purposes of reporting CAHPS for PQRS via a QCDR.

To the extent that further clarification on the distinction between a PQRS and a non-PQRS measure is necessary, we

will provide additional guidance on our Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/pqrs/index.html>.

Public Reporting of QCDR Quality Measures Data:

Furthermore, under our authority to establish the requirements for an entity to be considered a QCDR under section 1848(m)(3)(E)(i) of the Act, we established certain requirements for an entity to be considered a QCDR in the CY 2014 PFS final rule with comment period (78 FR 74467 through 74473). Under this same authority, we proposed here to add the following requirement that an entity must meet to serve as a QCDR under the PQRS for reporting periods beginning in 2015:

- Require that the entity make available to the public the quality measures data for which its eligible professionals report.

To clarify this proposal, we proposed that, at a minimum, the QCDR publicly report the following quality measures data information that we believe will give patients adequate information on the care provided by an eligible professional: The title and description of the measures that a QCDR reports for purposes of the PQRS, as well as the performance results for each measure the QCDR reports. We solicited and received the following public comment on this proposal:

Comment: Some commenters supported this proposal, as the commenters believed it was reasonable to require that this information be made available to the public. These commenters supported our proposal to defer to the QCDR in terms of what platform and in what manner this data may be made available to the public. Some commenters opposed this proposal, stating that the public reporting requirement was overly burdensome, and urged CMS to delay requiring the posting of measures data until the measures have been tested for validity and reliability. The commenters believed that CMS should not make substantial changes in the QCDR requirements as the QCDR option is new and the entities need time to familiarize themselves with the QCDR option before new requirements are established.

Response: With respect to the commenters who opposed this proposal and urged CMS not to make additional changes to the QCDR option while entities become more familiar with this option, we understand the commenters' concerns. However, we believe that transparency of data is a key component of a QCDR option. We believe that it is

appropriate to finalize this public reporting requirement at this time. In the CY 2014 PFS final rule, while we did not finalize our proposal that a QCDR have a plan to publicly report quality measures data, we noted that we encouraged "these qualified clinical data registries to move towards the public reporting of quality measures data" and that we planned to "establish such a requirement in the future" and would "revisit this proposed requirement as part of CY 2015 rulemaking" (78 FR 74471). Therefore, we believe that QCDRs were on notice that we would propose and finalize a requirement to make quality measures data available to the public beginning with the CY 2015 reporting.

However, although we do not believe we should further delay requiring public report of QCDR quality measures data, we do agree with the commenters on delaying public posting of measures information until a measure has been tested for validity and reliability. Therefore, we are providing an exception to this requirement for new measures (both PQRS and non-PQRS measures) that are in their first year of reporting by a QCDR under the PQRS. We define a measure being introduced in the PQRS for the first time as the first time a quality measure is either introduced in the PQRS measure set in rulemaking as a new measure for that reporting period or, for non-PQRS measures that can be reported by a QCDR, the first time a QCDR submits a measure (including its measure specifications) for reporting for the PQRS for the first time. Please note that, to the extent that a QCDR first reports on a non-PQRS measure that is already being reported by another QCDR, we would consider the measure a measure that is in its first year of reporting for that respective QCDR who is reporting the measure for the first time. We believe that providing QCDRs with one year to test and validate new measures provides sufficient time for QCDRs to find potential data issues and correct those issues prior to a measure's second year of reporting in the PQRS.

Based on the comments received and for the reasons stated in the proposed rule, we are finalizing this proposal to require that the entity make available to the public the quality measures data for which its eligible professionals report. However, as we explained above, we are providing an exception to this requirement for new PQRS and non-PQRS measures that are in their first year of reporting by a QCDR under the PQRS. Therefore, quality measure data for a PQRS or non-PQRS measure that is being reported by a QCDR in the

PQRS for the first time does not need to be posted for at least the initial year. After the initial year of reporting a new measure, as we believe it is important for a QCDR to be transparent in the quality performance of its eligible professionals, quality measures performance data for the measure (except for the data collected in the measure's first year of reporting in the PQRS) would be required to be made available to the public.

Please note that, in finalizing these requirements on public reporting, we defer to the entity in terms of the method it will use to publicly report the quality measures data it collects for the PQRS. For example, to meet this requirement, it would be sufficient for a QCDR to publicly report performance rates of eligible professionals through means such as board or specialty Web sites, or listserv dashboards or announcements. We also note that a QCDR would meet this public reporting requirement if the QCDR's measures data were posted on Physician Compare. In addition, we defer to the QCDR to determine whether to report performance results at the individual eligible professional level or aggregate the results for certain sets of eligible professionals who are in the same practice together (but who are not registered as a group practice for the purposes of PQRS reporting). We believe it is appropriate to allow a QCDR to publicly report performance results at an aggregate level for certain eligible professionals when those who are in the same practice contribute to the overall care provided to a patient.

- With respect to when the quality measures data must be publicly reported, we proposed that the QCDR must have the quality measures data by April 31 of the year following the applicable reporting period (that is, April 31, 2016, for reporting periods occurring in 2015). The deadline of April 31 will provide QCDRs with one month to post quality measures data and information following the March 31 deadline for the QCDRs to transmit quality measures data for purposes of the PQRS payment adjustments. Please note that we erroneously stated the proposed deadline as April 31, which does not exist in the calendar. We intended to propose a deadline that falls at the end of April—specifically, a deadline of April 30, not April 31, of the year following the applicable reporting period (that is, April 30, 2016, for reporting periods occurring in 2015). This was an inadvertent technical error, and we are therefore correcting this proposal here and our responses to comments below to reflect our intention

to propose a deadline of April 30 of the year following the applicable reporting period. We believe this does not materially modify this proposal, and as April 31 does not exist in the calendar, we believe that the public and commenters could reasonably infer that we intended to refer to the end of April in this proposed deadline, which is April 30 and thus reasonably foresee that we would adopt such a deadline. Therefore, we will address the comments and frame our responses below as they relate to an April 30 deadline of the year following the applicable reporting period (that is, April 30, 2016, for reporting periods occurring in 2015). We also proposed that this data be available on a continuous basis and be continuously updated as the measures undergo changes in measure title and description, as well as when new performance results are calculated. We solicited and received the following public comments on this proposal:

Comment: A few commenters opposed our proposal to require that a QCDR must have the quality measures data by April 30 of the year following the applicable reporting period. The commenter noted that any performance data publicly posted should be tested for accuracy and reliability. One commenter stated that QCDRs need more time following the QCDR submission deadline of March 31 to publicly post quality measures data. Another commenter noted that this timeline is more aggressive than that proposed on Physician Compare.

Response: We believe that the proposed April 30 deadline to make available quality measures data (except for PQRS and non-PQRS measures in their initial year of reporting under the PQRS) is reasonable, as we assume QCDRs would have already tested quality measures data and results for accuracy and reliability for the particular reporting period prior to submitting these quality measures data calculations and results by the March 31 submission deadline. However, we agree with the commenter on the need to provide accurate and reliable data prior to the data being publicly reported. Therefore, given concerns from commenters that April 30 does not provide the QCDRs with enough time to accurately post quality measures data, we are extending the deadline by which a QCDR must publicly report quality measures data outside of Physician Compare to the deadline by which Physician Compare posts QCDR quality measures data as discussed in section III.J above. That is, as indicated in Table 49 in section III.J.3 above, QCDRs

wishing to publicly report quality measures data outside of Physician Compare must do so in 2016.

Proposals Related to Collaboration of Entities To Become a QCDR:

Based on our experience with the qualifying entities wishing to become QCDRs for reporting periods occurring in 2014, we received feedback from many organizations who expressed concern that the entity wishing to become a QCDR may not meet the requirements of a QCDR solely on its own. Therefore, we provided the following proposals beginning in 2015 on situations where an entity may not meet the requirements of a QCDR solely on its own but, in conjunction with another entity, may be able to meet the requirements of a QCDR and therefore be eligible for qualification:

- We proposed to allow that an entity that uses an external organization for purposes of data collection, calculation or transmission may meet the definition of a QCDR so long as the entity has a signed, written agreement that specifically details the relationship and responsibilities of the entity with the external organizations effective as of January 1 the year prior to the year for which the entity seeks to become a QCDR (for example, January 1, 2014, to be eligible to participate for purposes of data collected in 2015). Entities that have a mere verbal, non-written agreement to work together to become a QCDR by January 1 the year prior to the year for which the entity seeks to become a QCDR would not fulfill this proposed requirement. We solicited and received the following public comment on this proposal:

Comment: A few commenters supported this proposal, as it allowed entities such as medical boards that may not have the technical capabilities to submit quality measures data calculations and results to CMS to collaborate with other entities.

Response: We appreciate the commenters' support. Based on the comments received, for the reasons stated here, and in the proposed rule, we are finalizing this proposal.

- In addition, we proposed that an entity that has broken off from a larger organization may be considered to be in existence for the purposes of QCDR qualification as of the earliest date the larger organization begins continual existence. We received questions from entities who used to be part of a larger organization but have recently become independent from the larger organization as to whether the entities would meet the requirement established in the CY 2014 PFS final rule with comment period that the entity be in

existence as of January 1 the year prior to the year for which the entity seeks to become a QCDR (78 FR 74467). For example, a registry that was previously a part of a larger medical society as of January 1, 2013, could have broken off from the medical society and become an independent registry in 2014. Likewise, a member of a medical society could create a registry separate from the medical society. As such, there would be concern as to whether that entity would meet the requirement of being in existence prior to January 1, 2013, to be considered for qualification for reporting periods occurring in 2014. In these examples, for purposes of meeting the requirement that the entity be in existence as of January 1 the year prior to the year for which the entity seeks to become a QCDR, we may consider this entity as being in existence as of the date the larger medical society was in existence. We solicited and received the following comments on this proposal:

Comment: Commenters supported this proposal.

Response: We appreciate the commenters' support and, based on the comments received and for the reasons stated above, we are finalizing this proposal.

Data Submission Deadline:

In the CY 2014 PFS final rule with comment period, in accordance with the submission deadline of quality measures data for qualified registries, we noted a deadline of the last Friday in February occurring after the end of the applicable reporting period to submit quality measures data to CMS (78 FR 74471). In accordance with our proposal to extend this deadline for qualified registries, we proposed to extend the deadline for QCDRs to submit quality measures data calculations and results by March 31 following the end of the applicable reporting period (that is, March 31, 2016, for reporting periods ending in 2015).

We solicited and received the following public comments on this proposal:

Comment: Commenters supported this proposal, as it would allow qualified registries an additional month to submit quality measures data and aligns with our proposal to extend the submission deadline for qualified registries.

Response: We appreciate the commenters' positive feedback. Based on the comments received and for the reasons stated in the proposed rule, we are finalizing our proposal to extend the deadline for QCDRs to submit quality measures data, including, but not limited to, calculations and results, to

March 31 following the end of the applicable reporting period (for example, March 31, 2016, for reporting periods ending in 2015).

d. Changes to the GPRO Web Interface

In the CY 2014 PFS final rule with comment period (78 FR 74456), we finalized our proposal to require "that group practices register to participate in the GPRO by September 30 of the year in which the reporting period occurs (that is September 30, 2014 for reporting periods occurring in 2014), as proposed." However, we noted that, in order "to respond to the commenters concerns to provide timelier feedback on performance on CG CAHPS in the future, we anticipate proposing an earlier deadline for group practices to register to participate in the GPRO in future years" (78 FR 74456). Indeed, to provide timelier feedback on performance on CAHPS for PQRS, we proposed to modify the deadline that a group practice must register to participate in the GPRO to June 30 of the year in which the reporting period occurs (that is, June 30, 2015, for reporting periods occurring in 2015). Specifically, although we still seek to provide group practices with as much time as feasible to decide whether to register to participate in the PQRS as a GPRO, we weigh this priority with others, such as our desire to provide more timely feedback to participants of the PQRS, as well as other CMS quality reporting programs such as the VM. Therefore, in an effort to provide timelier feedback, we proposed to change the deadline by which a group practice must register to participate in the GPRO to June 30 of the applicable 12-month reporting period (that is, June 30, 2015, for reporting periods occurring in 2015). This proposed change would allow us to provide timelier feedback while still providing group practices with over 6 months to determine whether they should participate in the PQRS GPRO or, in the alternative, participate in the PQRS as individual eligible professionals. Although this proposed GPRO registration deadline would provide less time for a group practice to decide whether to participate in the GPRO, we believe the benefit of providing timelier feedback reports outweighs this concern. We solicited and received the following public comments on these proposals:

Comment: Some commenters supported our proposal to shorten the deadline that a group practice must register to participate in the GPRO to June 30 of the year in which the reporting period occurs (that is, June 30, 2015, for reporting periods occurring in

2015) in order to provide timelier feedback reports. Other commenters opposed our proposal to shorten the deadline from September 30 to June 30, as the commenters believed that the extra time was needed to weigh the advantages and disadvantages of all the reporting options prior to registering for the GPRO and electing a reporting mechanism. One commenter noted that this is particularly important when reporting via EHR, as updates are required for EHR products. Some commenters requested that information for the various reporting mechanisms, such as the list of qualified registries for the reporting period, be made available earlier. Other commenters believed that it would be difficult for group practices to transition to an earlier registration date and requested that CMS delay finalizing this proposal to 2016. Other commenters stated that the proposed deadline would negatively affect group practices that change their Taxpayer Identification Number (TIN) after June 30, as the group practice would be required to report individually, adding to administrative and reporting burden.

Response: With respect to the comments opposing this proposal, we believe that June 30 provides group practices with ample time to decide to register to participate in the PQRS as a GPRO, as well as choose a reporting mechanism. With respect to the concern of having to choose a reporting option and not having all information on the PQRS reporting options prior to the June 30 deadline, we note that CMS makes numerous guidance documents available on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/pqrs/index.html>, and group practices can submit any questions to the QualityNet Help Desk at Qnetsupport@hcqis.org. With respect to some commenters' requests that information for the various reporting mechanisms, such as the list of qualified registries for the reporting period, be made available earlier, we note that the list of qualified registries for 2014—available at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2014QualifiedRegistries.pdf>—was made available in May 2014, prior to June 30, 2014, and we anticipate making the list of qualified registries for the given reporting period available in advance of the proposed June 30 registration deadline. With respect to the commenters who stated that the proposed deadline would negatively affect group practices that change their

Taxpayer Identification Numbers (TINs) after June 30, as the group practice would be required to report individually, adding to administrative and reporting burden, we understand this potential burden. We note that this proposed deadline is only 3 months earlier than the September 30 registration deadline we finalized in the CY 2014 PFS final rule (78 FR 74455). Therefore, we believe the issues associated with group practices that change their TINs would be exacerbated by finalizing the proposed June 30th registration deadline or ameliorated by keeping the current September 30 registration deadline. To the extent that finalizing an earlier deadline would increase the number of group practices affected by these issues, we believe that our interest in providing feedback sooner outweighs the concern of those group practices that change their TINs after June 30 not being able to participate in the GPRO. Based on the reasons stated here and in the proposed rule, we are finalizing our proposal to modify the deadline that a group practice must register to participate in the GPRO to June 30 of the year in which the reporting period occurs (that is, June 30, 2015, for reporting periods occurring in 2015). Please note that this GPRO registration deadline refers to all group practices wishing to participate in the GPRO using any reporting mechanism available for reporting in the GPRO (that is, GPRO web interface, registry, EHR, and/or CMS-certified survey vendor).

2. Criteria for the Satisfactory Reporting for Individual Eligible Professionals for the 2017 PQRS Payment Adjustment

Section 1848(a)(8) of the Act, as added by section 3002(b) of the Affordable Care Act, provides that for covered professional services furnished by an eligible professional during 2015 or any subsequent year, if the eligible professional does not satisfactorily report data on quality measures for covered professional services for the quality reporting period for the year, the fee schedule amount for services furnished by such professional during the year (including the fee schedule amount for purposes of determining a payment based on such amount) shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services. For 2016 and subsequent years, the applicable percent is 98.0 percent.

a. Criterion for the Satisfactory Reporting of Individual Quality Measures via Claims and Registry for Individual Eligible Professionals for the 2017 PQRS Payment Adjustment

In the CY 2014 PFS final rule with comment period (see Table 47 at 78 FR 74479), we finalized the following criteria for satisfactory reporting for the submission of individual quality measures via claims and registry for the 2014 PQRS incentive: For the 12-month reporting period for the 2014 PQRS incentive, the eligible professional would report at least 9 measures, covering at least 3 of the NQS domains, OR, if less than 9 measures apply to the eligible professional, report 1–8 measures, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. For an eligible professional who reports fewer than 9 measures covering less than 3 NQS domains via the claims- or registry-based reporting mechanism, the eligible professional would be subject to the measure application validity (MAV) process, which would allow us to determine whether the eligible professional should have reported quality data codes for additional measures.

To be consistent with the satisfactory reporting criterion we finalized for the 2014 PQRS incentive, for the 2017 PQRS payment adjustment, we proposed to modify § 414.90(j) and proposed the following criterion for individual eligible professionals reporting via claims and registry: For the 12-month reporting period for the 2017 PQRS payment adjustment, the eligible professional would report at least 9 measures, covering at least 3 of the NQS domains AND report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the measures reported, if the eligible professional sees at least 1 Medicare patient in a face-to-face encounter, as we proposed to define that term below, the eligible professional would report on at least 2 measures contained in the proposed cross-cutting measure set specified in Table 52. If less than 9 measures apply to the eligible professional, the eligible professional would report up to 8 measure(s), AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance

rate would not be counted (79 FR 40395).

We noted that, unlike the criterion we finalized for the 2014 PQRS incentive, we proposed to require an eligible professional who sees at least 1 Medicare patient in a face-to-face encounter, as we defined that term below, during the 12-month 2017 PQRS payment adjustment reporting period to report at least 2 measures contained in the cross-cutting measure set specified in Table 52. As we noted in the CY 2014 PFS proposed rule (78 FR 43359), we are dedicated to collecting data that provides us with a better picture of the overall quality of care furnished by eligible professionals, particularly for the purpose of having PQRS reporting being used to assess quality performance under the VM. We believe that requiring an eligible professional to report on at least 2 broadly applicable, cross-cutting measures will provide us with quality data on more varied aspects of an eligible professional's practice. We also noted that in its 2014 pre-rulemaking final report (available at http://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report-2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx), the Measure Applications Partnership (MAP) encouraged the development of a core measure set (see page 16 of the “MAP Pre-Rulemaking Report: 2014 Recommendations on Measures for More than 20 Federal Programs”). The MAP stated, “a core [measure set] would address critical improvement gaps, align payment incentives across clinician types, and reduce reporting burden.”

For what defines a “face-to-face” encounter, for purposes of reporting of at least 2 cross-cutting measures specified in Table 52, we proposed to determine whether an eligible professional had a “face-to-face” encounter by seeing whether the eligible professional billed for services under the PFS that are associated with face-to-face encounters, such as whether an eligible professional billed general office visit codes, outpatient visits, and surgical procedures. We would not include telehealth visits as face-to-face encounters for purposes of the required reporting of at least 2 cross-cutting measures specified in Table 52 (79 FR 40395 and 40396).

In addition, we understand that there may be instances where an eligible professional may not have at least 9 measures applicable to an eligible professional's practice. In this instance, like the criterion we finalized for the 2014 PQRS incentive (see Table 47 at 78

FR 74479), an eligible professional reporting on less than 9 measures would still be able to meet the satisfactory reporting criterion via claims and registry if the eligible professional reports on 1–8 measures, as applicable, to the eligible professional's practice. If an eligible professional reports on 1–8 measures, the eligible professional would be subject to the MAV process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures. In addition, the MAV will also allow us to determine whether a group practice should have reported on any of the cross-cutting measures specified in Table 52. The MAV process we proposed (79 FR 40396) to implement for claims and registry is the same process that was established for reporting periods occurring in 2014 for the 2014 PQRS incentive.

We solicited public comment on our satisfactory reporting criterion for individual eligible professionals reporting via claims or registry for the 2017 PQRS payment adjustment. The following is a summary of the comments we received regarding our proposal for satisfactory reporting criterion for individual eligible professionals reporting via claims or registry for the 2017 PQRS payment adjustment.

Comment: A few commenters supported our intention to move towards eliminating the claims-based reporting option, while the majority of the commenters opposed our proposals related to moving away from the claims-based reporting option. Some of these commenters noted that, for certain eligible professionals, the claims-based reporting mechanism remains the only option by which eligible professionals may report PQRS quality measures data, as many eligible professionals do not have the capabilities to report via EHR or registry. The commenters believe the claim-based reporting mechanism is a necessary option for eligible professionals with limited resources, such as solo practitioners. Should we intend to phase out this reporting mechanism, commenters urged a gradual phase out of the claims-based reporting mechanism.

Response: We appreciate the commenters' feedback. We understand the concerns associated with moving away from the claims-based reporting mechanism. For the 2017 PQRS payment adjustment, we are finalizing an option by which eligible professionals may meet the criteria for satisfactory reporting by using the claims-based reporting mechanism. Eligible professionals using the other

reporting mechanisms have seen greater success at meeting the criteria for satisfactory reporting for the PQRS. However, while we continue to eliminate measures available for reporting via claims, we understand the importance of maintaining the claims-based reporting mechanism as an option at this time. We understand that the claims-based reporting mechanism remains the most popular reporting mechanism. However, to streamline the PQRS reporting options, as well as to encourage reporting options where eligible professionals are found to be more successful in reporting, it is our intention to eliminate the claims-based reporting mechanism in future rulemaking. During this time, we encourage eligible professionals to use alternative reporting methods to become familiar with reporting mechanisms other than the claims-based reporting mechanism.

Comment: The majority of commenters opposed our proposal to require the reporting of 9 measures to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment. Some of these commenters noted that eligible professionals have been successful at meeting the criteria for satisfactory reporting for the PQRS incentives and payment adjustments in the past by reporting 3 measures, and increasing the number of measures to be reported would make it more difficult for these eligible professionals to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment. Other commenters also noted that certain eligible professionals do not have 9 measures covering 3 NQS domains to report. For these reasons, some commenters suggested a more gradual approach to requiring the reporting of at least 9 measures covering 3 NQS domains, such as requiring the reporting of 5 or 6 measures rather than 9 measures. A few commenters also recommended establishing a lower reporting threshold for those eligible professionals practicing in specialties for which few PQRS measures exist.

Response: While we understand the commenters concerns related to requiring the reporting of 9 measures covering up to 3 NQS domains, we believe we provided the public with adequate time to prepare for reporting criteria that requires the reporting of 9 measures. For example, we finalized criteria for the satisfactory reporting for the 2016 PQRS payment adjustment via claims and registry that only required the reporting of 3 measures covering 1 NQS domain (see Table 48 at 78 FR 74480). However, we also finalized criteria for the 2016 PQRS payment

adjustment using the claims- and registry-based reporting mechanisms that aligned with the following criteria we finalized for the 2014 PQRS incentive: Report at least 9 measures covering at least 3 NQS domains, OR, if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, report 1–9 measures covering 1–3 NQS domains, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measures applies (see Table 48 at 78 FR 74480). Additionally, in the CY 2014 PFS final rule, we noted that “it is our intent to ramp up the criteria for satisfactory reporting for the 2017 PQRS payment adjustment to be on par or more stringent than the criteria for satisfactory reporting for the 2014 PQRS incentive” (78 FR 74465). We believe that establishing criteria for the satisfactory reporting of the 2016 PQRS payment adjustment that are consistent with these proposed criteria, as well as signaling our intent to ramp up the satisfactory reporting criteria, provided enough advance notice to encourage eligible professionals to prepare to report 9 measures to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment.

Furthermore, with respect to those commenters concerned that an eligible professional may not have 9 measures covering at least 3 NQS domains applicable to his/her practice, in the proposed rule we noted that in this instance, like the criterion we finalized for the 2014 PQRS incentive (see Table 47 at 78 FR 74479), an eligible professional reporting on less than 9 measures would still be able to meet the satisfactory reporting criterion via claims and registry if the eligible professional reports on 1–8 measures, as applicable, to the eligible professional's practice. If an eligible professional reports on 1–8 measures, the eligible professional would be subject to the MAV process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures. In addition, the MAV process will also allow us to determine whether a group practice should have reported on any of the cross-cutting measures specified in Table 52. As such, under this proposed criteria for satisfactory reporting for the 2017 PQRS payment adjustment, an eligible professional who does not have at least 9 measures covering at least 3 NQS domains applicable to his/her practice may still meet the criteria for satisfactory reporting for the 2017 PQRS payment

adjustment provided that the eligible professional reports all measures as are applicable to his/her practice.

Based on the comments received and for the reasons stated above and in the proposed rule, we are finalizing our proposal to require the reporting of 9 measures covering at least 3 NQS domains to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment.

In the case that an eligible professional may not have at least 9 measures applicable to an eligible professional's practice, the eligible professional may still be able to meet the satisfactory reporting criterion via claims and/or registry for the 2017 PQRS payment adjustment if the eligible professional reports on 1–8 measures. The eligible professional would be required to report as many measures as are applicable to the eligible professional's practice. If reporting less than 9 measures covering 3 NQS domains, the eligible professional would be subject to the MAV process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures.

Comment: Some commenters provided general support for the option to report cross-cutting measures, as it may help bring alignment with respect to a set of measures all eligible professionals may report. However, most of these commenters believed that the reporting of cross-cutting measures should be voluntary, not mandatory. The majority of commenters opposed our proposal to require an eligible professional who sees at least 1 Medicare patient in a face-to-face encounter during the 12-month 2017 PQRS payment adjustment reporting period to report at least 2 measures contained in the proposed cross-cutting measure set specified in Table 52 (78 FR 40395). Some of these commenters believed that the proposed requirement is unfair, as the requirement to report on at least 2 cross-cutting measures placed an additional burden on certain specialists, such as those that do not provide primary care services, and not on others. Other commenters emphasized that the cross-cutting measures did not apply to many specialty practices. Contrary to these commenters, some commenters expressed support for this proposal. Some of those who supported, this proposal, however, recommended a more phased-in approach to the reporting of cross-cutting measures. One of these commenters recommended that the proposal be amended to require only the reporting of 1 measure in the cross-

cutting measure set. Some of these commenters were confused as to whether this proposal would increase the proposed number of measures to be reported to 11 measures.

Response: With respect to the commenters' concerns that requiring reporting of at least 2 cross-cutting measures for eligible professionals who see at least 1 Medicare patient in a face-to-face encounter, we understand that the cross-cutting measures we are finalizing in Table 52 are limited and should only apply to certain eligible professionals for which the measures apply. We believe we sufficiently exclude eligible professionals for which the cross-cutting measures do not apply by only proposing this requirement for eligible professionals who see at least 1 Medicare patient in a face-to-face encounter. We believe our interest in collecting data that are more varied to better capture the overall quality of care provided to patients as well as our desire to create a core set of measures for PQRS outweighs this concern. In the future, we will consider adding to this cross-cutting measures set so that more professionals that are eligible may be able to participate in the reporting of a core set of measures. With respect to the commenters who expressed concern that the proposed measures in the proposed cross-cutting measures set did not apply to many specialties, we note that an eligible professional would not be required to report on the measures contained in the cross-cutting measures set if none of the measures applied to the eligible professional's practice. With respect to taking a more phased-in approach to introducing the cross-cutting measure set, for the 2017 PQRS payment adjustment, we agree with these commenters and will therefore phase-in the requirement to report on cross-cutting measures by only requiring the reporting of 1 cross-cutting measure. We do note, however, that we believe that requiring the reporting of 2 measures in the cross-cutting measures set is not overly burdensome. Rather, we believe it helps eligible professionals narrow the choices of measures for which to report in the PQRS measure set. Regardless, we understand the commenters' concerns regarding the need for a gradual phase in of the cross-cutting measure set. Therefore, based on the comments received and for the reasons stated above and in the proposed rule, we are modifying our proposal to require that an eligible professional who sees at least 1 Medicare patient in a face-to-face encounter during the 12-month 2017 PQRS payment adjustment reporting

period report at least 1 measure contained in the cross-cutting measure set we are finalizing specified in Table 52. Please note that it is our intention to move towards requiring the reporting of more cross-cutting measures in the future.

Please also note that this does not bring the total number of measures required to be reported under this criterion to 10 measures. Rather, if an eligible professional sees at least 1 Medicare patient in a face-to-face encounter during the 12-month PQRS payment adjustment reporting period, 1 of the 9 measures the eligible professional reports must be measures contained in the cross-cutting measure set. Therefore, an eligible professional would report at least 1 cross-cutting measure and 8 additional PQRS measures covering 3 NQS domains.

In the instance where an eligible professional may not have at least 9 measures applicable to his/her practice, the eligible professional would still be required to report at least 1 cross-cutting measure, if applicable. As we noted, we believe we sufficiently exclude eligible professionals for which the cross-cutting measures do not apply by only proposing this requirement for eligible professionals who see at least 1 Medicare patient in a face-to-face encounter.

Comment: One commenter believes that the threshold of seeing 1 Medicare patient in a face-to-face encounter for the requirement to report on cross-cutting measures is too low. The commenter was concerned that this would further burden eligible professionals who rarely see Medicare patients.

Response: We understand the commenter's concern. However, as we believe in the importance of the cross-cutting measures set we are finalizing in Table 52, it is our desire to encourage reporting of the measures contained in the cross-cutting measures set when applicable. We proposed this threshold to exclude certain specialties that do not see Medicare patients. However, we expect those eligible professionals who see Medicare patients to report on the cross-cutting measures we specify in Table 52.

Comment: One commenter sought clarification on the definition of a face-to-face encounter by specifying which codes apply to this definition and urged that procedural encounters not be included in the list of face-to-face encounters.

Response: As we stated in the proposed rule, we will determine whether an eligible professional had a "face-to-face" encounter by seeing

whether the eligible professional billed for services under the PFS that are associated with face-to-face encounters, such as whether an eligible professional billed general office visit codes, outpatient visits, and surgical procedures. We would not include telehealth visits as face-to-face encounters for purposes of the requirements to report at least 1 cross-cutting measure specified in Table 52 (79 FR 40395 through 40396). While we will not provide the specific codes for what we define as a “face-to-face” encounter here, we will provide the codes and any additional guidance on the PQRS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html>.

Comment: Some commenters opposed our proposal to require that, to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment, an eligible professional reporting individual measures via claims or registry report each measure for at least 50 percent of the eligible professional’s Medicare Part B FFS patients seen during the reporting period to which the measure applies. The commenters noted that, particularly for those eligible professionals who see many patients, requiring the reporting of quality measures for more than 50 percent of the eligible professional’s Medicare Part B FFS patients is burdensome.

Response: We understand this concern, particularly with those eligible professionals who see a large number of patients. However, it is important to collect sufficient quality measures data to ensure an adequate sample. We believe that the 50 percent threshold provides us with an adequate sample to properly determine the quality of care provided. We also believe that requiring that an eligible professional report on at least 50 percent of his/her Medicare Part B FFS patients helps to prevent potential selection bias that could skew the representation of quality of care; while the potential for selection bias still remains, we were mindful of concerns about provider burden during this period where eligible professionals are still becoming accustomed to PQRS reporting. Based on the comments received and for the reasons stated above and in the proposed rule, we are finalizing our proposal to require that, to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment, an eligible professional reporting individual measures via claims or registry report each measure for at least 50 percent of the eligible professional’s Medicare Part B FFS

patients seen during the reporting period to which the measure applies.

Comment: Some commenters generally supported the MAV process. However, some commenters expressed the need to clarify the MAV process for both claims and registry as well as to provide greater transparency in this process.

Response: We understand the need to further clarify the MAV process for both claims and registry, as well as to provide transparency in this process. We believe the 2015 MAV process that we proposed for the 2017 PQRS payment adjustment is transparent, as it is very similar to the 2014 MAV process that we finalized for the 2014 PQRS incentive and 2016 PQRS payment adjustment, for which we have already provided detailed technical guidance. Specifically, we have made education and outreach documents, as well as the MAV measure clusters, (that is, sets of measures that determine when other measures could have been reported and therefore trigger use of the MAV process), available for the 2014 MAV process at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/AnalysisAndPayment.html>, and we will update these materials as necessary for the 2015 MAV process. Please note that, as the MAV process evolves, we expect to be able to provide further guidance to aid eligible professionals in understanding the MAV process. We will post additional clarifying information, including a document explaining the MAV process for 2015, on the PQRS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/pqrs/index.html>. We believe that posting this guidance as we have in years prior provides adequate transparency in this process. Moreover, should an eligible professional have further questions regarding the MAV process, he or she may contact our QualityNet Help Desk for more information. The contact information for the Help Desk can be found here: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/HelpDeskSupport.html>.

After reviewing the comments, we are finalizing our proposal to modify § 414.90(j) and finalize the following criterion for individual eligible professionals reporting via claims and registry:

For the 12-month reporting period for the 2017 PQRS payment adjustment, report at least 9 measures, covering at least 3 of the NQS domains AND report each measure for at least 50 percent of

the eligible professional’s Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the measures reported, if the eligible professional sees at least 1 Medicare patient in a face-to-face encounter, the eligible professional will report on at least 1 measure contained in the proposed cross-cutting measure set specified in Table 52. If less than 9 measures apply to the eligible professional, the eligible professional would report up to 8 measure(s), AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.

We understand that there may be instances where an eligible professional may not have at least 9 measures applicable to an eligible professional’s practice. In this instance, an eligible professional reporting on less than 9 measures would still be able to meet the satisfactory reporting criterion via claims and registry if the eligible professional reports on 1–8 measures, as applicable, to the eligible professional’s practice. If an eligible professional reports on 1–8 measures, the eligible professional would be subject to the MAV process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures. In addition, the MAV process will also allow us to determine whether a group practice should have reported on any of the cross-cutting measures specified in Table 52. The MAV process we will implement for claims and registry for the 2017 PQRS payment adjustment is the same process that was established for reporting periods occurring in 2014 for the 2014 PQRS incentive. For more information on the claims MAV process, please visit http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2014_PQRS_Claims_MeasureApplicabilityValidation_12132013.zip. For more information on the registry MAV process, please visit http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2014_PQRS_Registry_MeasureApplicabilityValidation_12132013.zip.

b. Criterion for Satisfactory Reporting of Individual Quality Measures via EHR for Individual Eligible Professionals for the 2017 PQRS Payment Adjustment

In the CY 2013 PFS final rule with comment period, we finalized the

following criterion for the satisfactory reporting for individual eligible professionals reporting individual measures via a direct EHR product that is CEHRT or an EHR data submission vendor product that is CEHRT for the 2014 PQRS incentive: Report 9 measures covering at least 3 of the NQS domains. If an eligible professional's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report all of the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data (see Table 47 at 78 FR 74479).

To be consistent with the criterion we finalized for the 2014 PQRS incentive, as well as to continue to align with the final criterion for meeting the clinical quality measure (CQM) component of achieving meaningful use under the Medicare EHR Incentive Program, we proposed to modify § 414.90(j) and proposed the following criterion for the satisfactory reporting for individual eligible professionals to report individual measures via a direct EHR product that is CEHRT or an EHR data submission vendor product that is CEHRT for the 2017 PQRS payment adjustment: The eligible professional would report 9 measures covering at least 3 of the NQS domains. If an eligible professional's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional would be required to report all of the measures for which there is Medicare patient data. An eligible professional would be required to report on at least 1 measure for which there is Medicare patient data.

We solicited public comment on this proposal.

The following is summary of the comments we received regarding our proposed criterion for the satisfactory reporting for individual eligible professionals to report individual measures via a direct EHR product that is CEHRT or an EHR data submission vendor product that is CEHRT for the 2017 PQRS payment adjustment.

Comment: The majority of commenters opposed our proposal to require the reporting of 9 measures to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment. Commenters also noted that certain eligible professionals do not have 9 measures covering 3 NQS domains to report. For these reasons, some commenters suggested a more gradual approach to requiring the reporting of at least 9 measures covering 3 NQS domains, such as requiring the

reporting of 5 or 6 measures rather than 9 measures. A few commenters also recommended establishing a lower reporting threshold for those eligible professionals practicing in specialties for which few PQRS measures exist.

Response: We understand the commenters' concerns. We note that we addressed these comments related to the reporting of 9 measures covering 3 domains as it relates to reporting via claims and registry above in section III.K.1.a., and that explanation also applies here with reporting via a direct EHR product that is CEHRT or EHR data submission vendor product that is CEHRT. Furthermore, we believe that aligning our EHR reporting options with the CQM component of meaningful use under the EHR Incentive Program actually reduces burden on eligible professionals when reporting. For the reasons explained above and to be consistent with the criterion we are finalizing for claims and registry as well as to be consistent with the requirements to meet the CQM component of meaningful use under the EHR Incentive Program, we are finalizing this proposal.

After reviewing the comments, we are finalizing our proposal as proposed to modify § 414.90(j) and to indicate the following criterion for the satisfactory reporting for individual eligible professionals to report individual measures via a direct EHR product that is CEHRT or an EHR data submission vendor product that is CEHRT for the 2017 PQRS payment adjustment: For the 12-month reporting period for the 2017 PQRS payment adjustment, report 9 measures covering at least 3 of the NQS domains. If an eligible professional's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional would be required to report all of the measures for which there is Medicare patient data. An eligible professional would be required to report on at least 1 measure for which there is Medicare patient data.

c. Criterion for Satisfactory Reporting of Measures Groups via Registry for Individual Eligible Professionals for the 2017 PQRS Payment Adjustment

In the CY 2013 PFS final rule with comment period, we finalized the following criterion for the satisfactory reporting for individual eligible professionals to report measures groups via registry for the 2014 PQRS incentive: For the 12-month reporting period for the 2014 PQRS incentive, report at least 1 measures group AND report each measures group for at least 20 patients, the majority (11 patients) of which must

be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted (see Table 47 at 78 FR 74479).

To be consistent with the criterion we finalized for the 2014 PQRS incentive, we proposed to modify § 414.90(j) to indicate the following criterion for the satisfactory reporting for individual eligible professionals to report measures groups via registry for the 2017 PQRS payment adjustment: For the 12-month reporting period for the 2017 PQRS payment adjustment, the eligible professional would report at least 1 measures group AND report each measures group for at least 20 patients, the majority (11 patients) of which would be required to be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate would not be counted.

Although we proposed a satisfactory reporting criterion for individual eligible professionals to report measures groups via registry for the 2017 PQRS payment adjustment that is consistent with criterion finalized for the 2014 PQRS incentive, please note that in section III.K of this final rule with comment period, we are changing the definition of a PQRS measures group.

We solicited but received no public comment on our proposed satisfactory reporting criterion for individual eligible professionals reporting measures groups via registry for the 2017 PQRS payment adjustment. Therefore, we are finalizing our proposal as proposed to modify § 414.90(j) to indicate the following criterion for the satisfactory reporting for individual eligible professionals to report measures groups via registry for the 2017 PQRS payment adjustment: For the 12-month reporting period for the 2017 PQRS payment adjustment, report at least 1 measures group AND report each measures group for at least 20 patients, the majority (11 patients) of which are required to be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.

3. Satisfactory Participation in a QCDR by Individual Eligible Professionals

Section 601(b) of the ATRA amended section 1848(m)(3) of the Act, by redesignating subparagraph (D) as subparagraph (F) and adding new subparagraphs (D) and (E), to provide for a new standard for individual eligible professionals to satisfy the PQRS beginning in 2014, based on satisfactory participation in a QCDR.

a. Criterion for the Satisfactory Participation for Individual Eligible Professionals in a QCDR for the 2017 PQRS Payment Adjustment

Section 1848(a)(8) of the Act provides that for covered professional services furnished by an eligible professional during 2015 or any subsequent year, if the eligible professional does not satisfactorily report data on quality measures for covered professional services for the quality reporting period for the year, the fee schedule amount for services furnished by such professional during the year shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services. For 2016 and subsequent years, the applicable percent is 98.0 percent.

Section 1848(m)(3)(D) of the Act, as added by section 601(b) of the ATRA, authorizes the Secretary to treat an individual eligible professional as satisfactorily submitting data on quality measures under section 1848(m)(3)(A) of the Act if, in lieu of reporting measures under section 1848(k)(2)(C) of the Act, the eligible professional is satisfactorily participating in a QCDR for the year. “Satisfactory participation” is a new standard under the PQRS and is a substitute for the underlying standard of “satisfactory reporting” data on covered professional services that eligible professionals must meet to avoid the PQRS payment adjustment. Currently, § 414.90(e)(2) states that individual eligible professionals must be treated as satisfactorily reporting data on quality measures if the individual eligible professional satisfactorily participates in a QCDR.

In the CY 2014 PFS final rule with comment period, although we finalized satisfactory participation criteria for the 2016 PQRS payment adjustment that are less stringent than the satisfactory participation criteria we finalized for the 2014 PQRS incentive, we noted that it was “our intention to fully move towards the reporting of 9 measures covering at least 3 domains to meet the criteria for satisfactory participation for the 2017 PQRS payment adjustment” (78 FR 74477). Specifically, we finalized the following two criteria for the satisfactory participation in a QCDR for the 2014 PQRS incentive at § 414.90(i)(3): For the 12-month 2014 reporting period, report at least 9 measures available for reporting under the QCDR covering at least 3 of the NQS domains, and report each measure for at least 50 percent of the eligible professional’s applicable patients. Of the measures reported via a QCDR, the

eligible professional must report on at least 1 outcome measure.

To be consistent with the number of measures reported for the satisfactory participation criterion we finalized for the 2014 PQRS incentive, for purposes of the 2017 PQRS payment adjustment (which would be based on data reported during the 12-month period that falls in CY 2015), we proposed to modify § 414.90(k) to add the following criteria for individual eligible professionals to satisfactorily participate in a QCDR for the 2017 PQRS payment adjustment: For the 12-month reporting period for the 2017 PQRS payment adjustment, the eligible professional would report at least 9 measures available for reporting under a QCDR covering at least 3 of the NQS domains, AND report each measure for at least 50 percent of the eligible professional’s patients. Of these measures, the eligible professional would report on at least 3 outcome measures, OR, if 3 outcomes measures are not available, report on at least 2 outcome measures and at least 1 of the following types of measures—resource use, patient experience of care, or efficiency/appropriate use.

Unlike the satisfactory participation criteria that were established for the 2014 PQRS incentive, we proposed to modify § 414.90(k)(4) to require that an eligible professional report on not only 1 but at least 3 outcome measures (or, 2 outcome measures and at least 1 resource use, patient experience of care, or efficiency/appropriate use if 3 outcomes measures are not available). We proposed this increase because it is our goal to, when appropriate, move towards the reporting of more outcome measures. We believe the reporting of outcome measures (for example, unplanned hospital readmission after a procedure) better captures the quality of care an eligible professional provides than, for example, process measures (for example, whether a Hemoglobin A1c test was performed for diabetic patients). In establishing this proposal, we understood that a QCDR may not have 3 outcomes measures within its quality measure data set. Therefore, as an alternative to a third outcome measure, we proposed to allow an eligible professional to report on at least 1 resource use, patient experience of care, or efficiency/appropriate use measure in lieu of an outcome measure.

We solicited public comment on these proposals. The following is summary of the comments we received regarding on these proposals.

Comment: Commenters generally urged more flexibility in allowing QCDRs to determine reporting criteria under this option.

Response: While we agree that QCDRs should generally be given some flexibility when participating in the PQRS, we do not agree that QCDRs be given flexibility in determining reporting criteria. We believe it is necessary to have consistent reporting criteria, so that quality measures data on eligible professionals may be more easily compared for purposes of other programs that use PQRS quality data to rate and compare eligible professionals, such as the VM.

Comment: The majority of commenters opposed our proposal to require the reporting of 9 measures to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment. Commenters also noted that certain eligible professionals do not have 9 measures covering 3 NQS domains to report. For these reasons, some commenters suggested a more gradual approach to requiring the reporting of at least 9 measures covering 3 NQS domains, such as requiring the reporting of 5 or 6 measures rather than 9 measures.

Response: While we understand the commenters’ concerns related to requiring the reporting of 9 measures covering up to 3 NQS domains, we believe we provided the public with adequate time to prepare to reporting criteria that requires the reporting of 9 measures. For example, we finalized criteria for satisfactory participation for the 2016 PQRS payment adjustment via a QCDR that aligned with the criteria we finalized for the 2014 PQRS incentive: For the 12-month 2016 PQRS payment adjustment reporting period, report at least 9 measures covering at least 3 NQS domains AND report each measure for at least 50 percent of the applicable patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. Of the measures reported via a QCDR, the eligible professional must report on at least 1 outcome measure (78 FR 74478). Additionally, in the CY 2014 PFS final rule, we noted that “it is our intent to ramp up the criteria for satisfactory reporting for the 2017 PQRS payment adjustment to be on par or more stringent than the criteria for satisfactory reporting for the 2014 PQRS incentive” (78 FR 74465). We believe that establishing criteria for the satisfactory reporting of the 2017 PQRS payment adjustment that are consistent with these proposed criteria as well as signaling our intent to ramp up the satisfactory reporting criteria provided enough advance notice to encourage eligible professionals to prepare to report 9 measures to meet the criteria for

satisfactory reporting for the 2017 PQRS payment adjustment. Based on the comments received and for the reasons stated, we are finalizing our proposal for QCDRs to require the reporting of 9 measures to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment.

Comment: Some commenters opposed our proposal to require that, to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment, an eligible professional reporting individual measures via a QCDR report each measure for at least 50 percent of the eligible professional's patients seen during the reporting period to which the measure applies. The commenters noted that, particularly for those eligible professionals who see many patients, requiring the reporting of quality measures for more than 50 percent of the eligible professional's patients is an enormous burden.

Response: We understand this concern, particularly with respect to those eligible professionals who see a large number of patients. However, it is important to collect sufficient quality measures data to ensure an adequate sample. We also believe that requiring that an eligible professional report on at least 50 percent of his/her Medicare Part B FFS patients helps to prevent potential selection bias that could skew the representation of quality of care; while the potential for selection bias still remains, we were mindful of concerns about provider burden during this period where eligible professionals are still becoming accustomed to PQRS reporting. Based on the comments received and for the reasons stated above and in the proposed rule, we are finalizing our proposal to require that, to meet the criteria for satisfactory participation for the 2017 PQRS payment adjustment, an eligible professional reporting individual measures via a QCDR report each measure for at least 50 percent of the eligible professional's patients seen during the reporting period to which the measure applies. Please note that, unlike the claims and registry-based reporting mechanisms, if using a QCDR, an eligible professional must report on ALL (Medicare and non-Medicare) patients.

Comment: The majority of commenters opposed our proposal to report on at least 3 outcome measures, as many of these commenters believed QCDRs might not have 3 outcome measures available to report. The commenters urged a more gradual approach to the reporting of outcome measures via a QCDR.

Response: We understand the commenters' concerns. To accommodate these concerns, we are modifying this proposal to require only reporting of 2 outcome measures or, if 2 outcome measures are not available, report on 1 outcome measure and 1 of the following types of measures—resource use, patient experience of care, efficiency/appropriate use or patient safety. We believe this compromise still raises the bar on the types of measures eligible professionals must report, but allows QCDRs that may only have 1 outcome measure available to still qualify and participate in the PQRS. We note, however, our intention to increase the number of outcome measures that must be reported in the future.

In addition, we note that we are adding another category—patient safety—of measures that an eligible professional may report in lieu of an outcome measure. While we did not include this category before, we believe the addition of the patient safety category is appropriate, as we believe that it is equally important to measure patient safety, as it is to measure resource use, patient experience of care, or appropriate use. Furthermore, we believe the addition of another category of measures that may be reported in lieu of an outcome measure benefits eligible professionals and QCDRs and is responsive to some of the commenters' concerns regarding having enough measures to report, as it provides more options in terms of the measures an eligible professional may report in lieu of an outcome measure. We define the term “patient safety” as it applies to QCDRs in the QCDR measure section in III.K.6 below.

As a result of the comments, we are revising our proposal to modify § 414.90(k) to indicate the following criterion for satisfactory participation in a QCDR for the 2017 PQRS payment adjustment: For the 12-month reporting period for the 2017 PQRS payment adjustment, report at least 9 measures available for reporting under a QCDR covering at least 3 of the NQS domains, AND report each measure for at least 50 percent of the eligible professional's patients. Of these measures, the eligible professional would report on at least 2 outcome measures, OR, if 2 outcomes measures are not available, report on at least 1 outcome measure and at least 1 of the following types of measures—resource use, patient experience of care, efficiency/appropriate use, or patient safety.

4. Criteria for Satisfactory Reporting for Group Practices Selected To Participate in the Group Practice Reporting Option (GPRO)

In lieu of reporting measures under section 1848(k)(2)(C) of the Act, section 1848(m)(3)(C) of the Act provides the Secretary with the authority to establish and have in place a process under which eligible professionals in a group practice (as defined by the Secretary) shall be treated as satisfactorily submitting data on quality measures. Accordingly, this section III.K.4 contains our satisfactory reporting criteria for group practices selected to participate in the GPRO. Please note that, for a group practice to participate in the PQRS GPRO in lieu of participating as individual eligible professionals, a group practice is required to register to participate in the PQRS GPRO. For more information on GPRO participation, please visit http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Group_Practice_Reporting_Option.html. For more information on registration, please visit <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Self-Nomination-Registration.html>.

a. Criteria for Satisfactory Reporting on PQRS Quality Measures Via the GPRO Web Interface for the 2017 PQRS Payment Adjustment

Consistent with the group practice reporting requirements under section 1848(m)(3)(C) of the Act, we proposed to modify § 414.90(j) to incorporate the following criterion for the satisfactory reporting of PQRS quality measures for group practices registered to participate in the GPRO for the 12-month reporting period for the 2017 PQRS payment adjustment using the GPRO web interface for groups practices of 25–99 eligible professionals: The group practice would report on all measures included in the web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice would report on 100 percent of assigned beneficiaries. In other words, we understand that, in some instances, the sampling methodology CMS provides will not be able to assign at least 248 patients on which a group practice may report, particularly those group practices on the smaller end of the range of 25–99

eligible professionals. If the group practice is assigned less than 248 Medicare beneficiaries, then the group practice would report on 100 percent of its assigned beneficiaries. A group practice would be required to report on at least 1 measure for which there is Medicare patient data.

In addition, we proposed to modify § 414.90(j) to incorporate the following criteria for the satisfactory reporting of PQRS quality measures for group practices that registered to participate in the GPRO for the 12-month reporting period for the 2017 PQRS payment adjustment using the GPRO web interface for groups practices of 100 or more eligible professionals: The group practice would report all CAHPS for PQRS survey measures via a certified survey vendor. In addition, the group practice would report on all measures included in the GPRO web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice would report on 100 percent of assigned beneficiaries. A group practice would be required to report on at least 1 measure for which there is Medicare patient data.

To maintain consistency in this reporting criteria, we note that this criteria is similar to the criterion we finalized for the satisfactory reporting of PQRS quality measures for group practices selected to participate in the GPRO for the 12-month reporting periods for the 2013 and 2014 PQRS incentives for group practices of 100 or more eligible professionals in the CY 2013 PFS final rule with comment period (see Table 49 at 78 FR 74486). However, we proposed to reduce the patient sample size on which a group practice is required to report quality measures data from 411 to 248. We examined the sample size of this reporting criterion and determined that the sample size we proposed reduces provider reporting burden while still allowing for statistically valid and reliable performance results. For the 25–99 sized groups reporting via the web interface, we recognized the proposal to move from reporting 218 to 248 patients per sample represents a slight increase in reporting. However, based on experience with the 218 count and subsequent statistical analysis, we believe that there are increased performance reliabilities and validities gained when changing the minimum reporting requirement to 248. We believe statistical reliability and validity

is extremely important when measuring provider performance, particularly given the implications of the Physician VM and Physician Compare public reporting, discussed in section III.N and section III.J respectively. Therefore, we believe this criterion improves on the criterion previously finalized.

For assignment of patients for group practices reporting via the GPRO web interface, in previous years, we have aligned with the Medicare Shared Savings Program methodology of beneficiary assignment (see 77 FR 69195). We note that, in section III.N. of the CY 2015 PFS proposed rule, we proposed to use a beneficiary attribution methodology for the VM for the claims-based quality measures and cost measures that is slightly different from the Medicare Shared Savings Program methodology, namely (1) eliminating the primary care service pre-step that is statutorily required for the Shared Savings Program and (2) including NPs, PA, and CNSs in step 1 rather than in step 2 of the attribution process. We believe that aligning with the VM's proposed method of attribution is appropriate, as the VM is directly tied to participation in the PQRS. Therefore, to achieve further alignment with the VM and for the reasons proposed in section III.N., we proposed to adopt the attribution methodology changes proposed for the VM into the GPRO web interface beneficiary assignment methodology. We invited public comment on these proposals. The following is summary of the comments we received regarding on these proposals.

Comment: A majority of the commenters supported our proposal for a group practice of 25 or more eligible professionals using the GPRO web interface to report on a patient sample of 248. With respect to having group practices of 100 or more eligible professionals report on a patient sample of 248 in lieu of 411 (the required patient sample for group practices of 100 or more eligible professionals for the 2014 PQRS incentive), the commenters agreed that this would reduce the reporting burden while still ensuring statistically valid and reliable performance results.

Response: We appreciate the commenters' feedback. Based on the positive comments received and for the reasons stated in the proposed rule, we are finalizing this proposal. Therefore, to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment for a group practice of 25 or more eligible professionals using the GPRO web interface, a group practice

would be required to report on at least 248 patients.

As a result of the comments, we are finalizing the following criteria for satisfactory reporting for the 2017 PQRS payment adjustment for group practices comprised of 25 to 99 eligible professionals using the GPRO web interface: report on all measures included in the web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. In other words, we understand that, in some instances, the sampling methodology we provide will not be able to assign at least 248 patients on which a group practice may report, particularly those group practices on the smaller end of the range of 25–99 eligible professionals. If the group practice is assigned less than 248 Medicare beneficiaries, then the group practice must report on 100 percent of its assigned beneficiaries. A group practice must report on at least 1 measure for which there is Medicare patient data.

In addition, we note that, in the past, we have not provided guidance on those group practices that choose the GPRO web interface to report PQRS quality measures but have seen no Medicare patients for which the GPRO measures are applicable, or if they have no (that is, 0 percent) responses for a particular module or measure. Since we are moving solely towards the implementation of PQRS payment adjustments, we sought to clarify this scenario here. If a group practice has no Medicare patients for which any of the GPRO measures are applicable, the group practice will not meet the criteria for satisfactory reporting using the GPRO web interface. Therefore, to meet the criteria for satisfactory reporting using the GPRO web interface, a group practice must be assigned and have sampled at least 1 Medicare patient for any of the applicable GPRO web interface measures (specified in Table 52). If a group practice does not typically see Medicare patients for which the GPRO web interface measures are applicable, we advise the group practice to participate in the PQRS via another reporting mechanism.

Please note that the discussion in this section III.K.4.a is limited to the criteria for satisfactory reporting for the 2017 PQRS payment adjustment for group practices comprised of 25–99 eligible

professionals who register to participate in the GPRO and who have at least 1 Medicare patient for which any of the GPRO measures are applicable. As we discuss in greater detail in section III.K.4 below, since we are requiring that group practices report on CAHPS for PQRS, the final criteria for group practices comprised of 100 or more eligible professionals are addressed in section III.K.4.c.

b. Criteria for Satisfactory Reporting on Individual PQRS Quality Measures for Group Practices Registered To Participate in the GPRO via Registry and EHR for the 2017 PQRS Payment Adjustment

For registry reporting in the GPRO, in the CY 2014 PFS final rule with comment period (see Table 49 at 78 FR 74486), we finalized the following satisfactory reporting criteria for the submission of individual quality measures via registry for group practices comprised of 2 or more eligible professionals in the GPRO for the 2014 PQRS incentive: Report at least 9 measures, covering at least 3 of the NQS domains, OR, if less than 9 measures covering at least 3 NQS domains apply to the group practice, report 1–8 measures covering 1–3 NQS domains for which there is Medicare patient data, AND report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. In the CY 2014 PFS final rule with comment period, we signaled that it was "our intent to ramp up the criteria for satisfactory reporting for the 2017 PQRS payment adjustment to be on par or more stringent than the criteria for satisfactory reporting for the 2014 PQRS incentive" (78 FR 74465).

Consistent with the criterion finalized for the 2014 PQRS incentive and the group practice reporting requirements under section 1848(m)(3)(C) of the Act, for those group practices that choose to report using a qualified registry, we modified § 414.90(j) to include the following satisfactory reporting criterion via qualified registry for ALL group practices who select to participate in the GPRO for the 2017 PQRS payment adjustment: The group practice would report at least 9 measures, covering at least 3 of the NQS domains. Of these measures, if a group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice would report on at least 2 measures in the cross-cutting measure set specified in Table 52. If less than 9 measures covering at least 3 NQS domains apply

to the eligible professional, the group practice would report up to 8 measures covering 1–3 NQS domains for which there is Medicare patient data, AND report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.

As with individual reporting, we understand that there may be instances where a group practice may not have at least 9 measures applicable to a group practice's practice. In this instance, like the criterion we finalized for the 2014 PQRS incentive (see Table 49 at 78 FR 74486), a group practice reporting on less than 9 measures would still be able to meet the satisfactory reporting criterion via registry if the group practice reports on as many measures as are applicable to the group practice's practice. If a group practice reports on less than 9 measures, the group practice would be subject to the MAV process, which would allow us to determine whether a group practice should have reported quality data codes for additional measures and/or measures covering additional NQS domains. Please note that this MAV process does not apply to the application of the cross-cutting measure reporting requirement, as we require that all group practices report on at least 1 cross-cutting measure if an eligible professional in the group practice see at least sees at least 1 Medicare patient in a face-to-face encounter. The MAV process we proposed to implement for registry reporting is the same process that was established for reporting periods occurring in 2014 for the 2014 PQRS incentive. For more information on the registry MAV process, please visit http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2014_PQRS_Registry_MeasureApplicabilityValidation_12132013.zip.

For EHR reporting, consistent with the criterion finalized for the 2014 PQRS incentive that aligns with the criteria established for meeting the CQM component of meaningful use under the Medicare EHR Incentive Program and in accordance with the group practice reporting requirements under section 1848(m)(3)(C) of the Act, for those group practices that choose to report using an EHR, we proposed to modify § 414.90(j) to indicate the following satisfactory reporting criterion via a direct EHR product that is CEHRT or an EHR data submission vendor that is CEHRT for ALL group practices who select to

participate in the GPRO for the 2017 PQRS payment adjustment: For the 12-month reporting period for the 2017 PQRS payment adjustment, the group practice would report 9 measures covering at least 3 domains. If the group practice's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is patient data. A group practice must report on at least 1 measure for which there is Medicare patient data. We invited public comment on these proposals. The following is summary of the comments we received regarding on these proposals.

Comment: The majority of commenters opposed our proposal to require the reporting of 9 measures to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment. Some commenters supported the reporting of 9 measures when using the EHR reporting mechanisms, indicating that the proposed criterion aligns with the criterion for meeting the eCQM component of meaningful use under the EHR Incentive Program. Some of the commenters opposing this proposal noted that group practices have been successful at meeting the criteria for satisfactory reporting for the PQRS incentives and payment adjustments in the past by reporting 3 measures, and increasing the number of measures to be reported would make it more difficult for these group practices to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment. Other commenters also noted that certain group practices do not have 9 measures covering 3 NQS domains to report. For these reasons, some commenters suggested a more gradual approach to requiring the reporting of at least 9 measures covering 3 NQS domains, such as requiring the reporting of 5 or 6 measures rather than 9 measures. A few commenters also recommended establishing a lower reporting threshold for those group practices practicing in specialties for which few PQRS measures exist.

Response: While we understand the commenters concerns related to requiring the reporting of 9 measures covering up to 3 NQS domains, we believe we provided the public with adequate time to prepare to reporting criteria that requires the reporting of 9 measures. For example, we finalized criteria for the satisfactory reporting for the 2016 PQRS payment adjustment via registry that only required the reporting of 3 measures covering 1 NQS domain (see Table 50 at 78 FR 74486). However,

we also finalized criteria for the 2016 PQRS payment adjustment using the registry- and EHR-based reporting mechanisms that aligned with the criteria we finalized for the 2014 PQRS incentive that generally required reporting of at least 9 measures covering at least 3 NQS domains. Additionally, in the CY 2014 PFS final rule, we noted that “it is our intent to ramp up the criteria for satisfactory reporting for the 2017 PQRS payment adjustment to be on par or more stringent than the criteria for satisfactory reporting for the 2014 PQRS incentive” (78 FR 74465). We believe that establishing criteria for the satisfactory reporting of the 2016 PQRS payment adjustment that are consistent with this proposed criteria, as well as signaling our intent to ramp up the satisfactory reporting criteria, provided enough advanced notice to encourage eligible professionals to prepare to report 9 measures to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment.

Furthermore, with respect to those commenters concerned that a group practice may not have 9 measures covering at least 3 NQS domains applicable to his or her practice, in the proposed rule, with respect to reporting via registry, we noted that “as with individual reporting, we understand that there may be instances where a group practice may not have at least 9 measures applicable to a group practice’s practice. In this instance, like the criterion we finalized for the 2014 PQRS incentive (see Table 49 at 78 FR 74486), a group practice reporting on less than 9 measures would still be able to meet the satisfactory reporting criterion via registry if the group practice reports on as many measures as are applicable to the group practice’s practice” (79 FR 40399). Under this proposed criterion for satisfactory reporting for the 2017 PQRS payment adjustment for group practices reporting via registry, a group practice who does not have at least 9 measures covering at least 3 NQS domains applicable to the practice may still meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment provided that the group practice reports all measures as are applicable to his or her practice.

With respect to reporting via an EHR, we noted that if the group practice’s CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

Based on the comments received and for the reasons stated above and in the

proposed rule, we are finalizing our proposal to require the reporting of 9 measures covering at least 3 NQS domains via registry and EHR to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment.

Comment: Commenters provided the same comments for requiring the reporting of cross-cutting measures for group practice reporting as individual reporting in section III.K.2.a. Some commenters provided general support for the option to report cross-cutting measures via registry, as it may help bring alignment with respect to a set of measures all group practices may report. However, most of these commenters believed that the reporting of cross-cutting measures should be voluntary, not mandatory. The majority of commenters opposed our proposal to require a group practice that sees at least 1 Medicare patient in a face-to-face encounter during the 12-month 2017 PQRS payment adjustment reporting period to report at least 2 measures contained in the proposed cross-cutting measure set specified in Table 21 of the CY 2015 PFS proposed rule (79 FR 40395). Some of these commenters believed the proposed requirement to be unfair, as the requirement to report on at least 2 cross-cutting measures placed an additional burden on certain specialists and not others. Other commenters emphasized that the cross-cutting measures did not apply to many specialty practices. Contrary to these commenters, some commenters expressed support for this proposal. Some of those who supported, this proposal, however, recommended a more phased-in approach to the reporting of cross-cutting measures. One of these commenters recommended that the proposal be amended to require only the reporting of 1 measure in the cross-cutting measure set. Some of these commenters were confused as to whether this proposal would increase the proposed number of measures to be reported to 11 measures.

Response: Please note that our responses to these comments are the same responses we provided previously regarding our proposal to require the reporting of cross-cutting measures for individual reporting. Therefore, based on the comments received and for the reasons stated previously and in the proposed rule, we are modifying our proposal to require that a group practice who sees at least 1 Medicare patient in a face-to-face encounter during the 12-month 2017 PQRS payment adjustment reporting period report at least 1 measure contained in the cross-cutting measure set we are finalizing specified in Table 52.

Please note that this does not bring the total number of measures required to be reported under this criterion to 10 measures. Rather, if a group practice sees at least 1 Medicare patient in a face-to-face encounter during the 12-month PQRS payment adjustment reporting period, 1 of the 9 measures the group practice reports must be measures contained in the cross-cutting measure set. Therefore, a group practice would report at least 1 cross-cutting measure and 8 additional PQRS measures.

In the instance where a group practice may not have at least 9 measures applicable to his/her practice, the eligible professional would still be required to report at least 1 cross-cutting measure, if applicable. If a group practice reporting on less than 9 measures does not have at least 1 cross-cutting measure applicable to his or her practice, then the group practice would report on as many measures as our applicable to his or her practice.

Comment: One commenter believes that the threshold of seeing 1 Medicare patient in a face-to-face encounter for the requirement to report on cross-cutting measures is too low. The commenter was concerned that this would further burden group practices who rarely see Medicare patients.

Response: We understand the commenter’s concern. However, as we believe in the importance of the cross-cutting measures set we are finalizing in Table 52, it is our desire to encourage reporting of the measures contained in the cross-cutting measures set when applicable. We proposed this threshold to exclude certain specialties that do not see Medicare patients. However, we expect those group practices that see Medicare patients to report on the cross-cutting measures we specify in Table 52.

Comment: One commenter sought clarification on the definition of a face-to-face encounter by specifying which codes apply to this definition and urged that procedural encounters not be included in the list of face-to-face encounters.

Response: As we stated in the proposed rule, we will determine whether an eligible professional in a group practice had a “face-to-face” encounter by seeing whether the eligible professional billed for services under the PFS that are associated with face-to-face encounters, such as whether an eligible professional billed general office visit codes, outpatient visits, and surgical procedures. We would not include telehealth visits as face-to-face encounters for purposes of the proposals requiring reporting of at least 2 cross-cutting measures specified in Table 52. While we will not provide the specific

codes for what we define as a “face-to-face” encounter here, we will provide additional guidance on the PQRS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html>.

Comment: Some commenters opposed our proposal to require that, to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment, a group practice reporting individual measures via registry report each measure for at least 50 percent of the group practice’s Medicare Part B FFS patients seen during the reporting period to which the measure applies. The commenters noted that, particularly for those group practices that see many patients, requiring the reporting of quality measures for more than 50 percent of the group practice’s Medicare Part B FFS patients is an enormous burden.

Response: We understand this concern, particularly with those group practices that see a large number of patients. However, it is important to collect sufficient quality measures data to ensure an adequate sample. We also believe that requiring that a group practice report on at least 50 percent of its Medicare Part B FFS patients helps to prevent potential selection bias that could skew the representation of quality of care; while the potential for selection bias still remains, we were mindful of concerns about provider burden during this period where group practices are still becoming accustomed to PQRS reporting. Based on the comments received and for the reasons stated above and in the proposed rule, we are finalizing our proposal to require that, to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment, a group practice reporting individual measures via registry report each measure for at least 50 percent of the group practice’s Medicare Part B FFS patients seen during the reporting period to which the measure applies.

Comment: Some commenters generally supported the MAV process. However, some commenters expressed the need to clarify the MAV process for registry as well as to provide greater transparency in this process.

Response: We understand the need to clarify further the MAV process for both claims and registry. Please note that, as the MAV process evolves, we expect to be able to provide further guidance to aid group practices in understanding the MAV process. We will post additional clarifying information, including a “made simple” document on the MAV process for 2015 on the PQRS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/pqrs/index.html>. We

believe that posting this guidance as we have in years prior provides adequate transparency in this process. Moreover, should a group practice have further questions regarding the MAV process, he/she may contact our QualityNet Help Desk for more information. The contact information for the Help Desk can be found here: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/HelpDeskSupport.html>.

Because of the comments, we are finalizing our proposal to modify § 414.90(j) and finalize the following criteria for satisfactory reporting for group practices participating in the GPRO via registry and EHR for the 2017 PQRS payment adjustment:

For group practices comprised of 2–99 eligible professionals reporting for the 12-month reporting period for the 2017 PQRS payment adjustment via registry, report at least 9 measures, covering at least 3 of the NQS domains. Of these measures, if a group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice would report on at least 1 measure in the cross-cutting measure set specified in Table 52. If less than 9 measures covering at least 3 NQS domains apply to the group practice, the group practice would report up to 8 measures covering 1–3 NQS domains for which there is Medicare patient data, AND report each measure for at least 50 percent of the group’s Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.

We understand that there may be instances where a group practice may not have at least 9 measures applicable to an eligible professional’s practice. In this instance, a group practice reporting on less than 9 measures would still be able to meet the satisfactory reporting criterion via claims and registry if the group practice reports on 1–8 measures, as applicable, to the group’s practice. If a group practice reports on 1–8 measures, the group practice would be subject to the MAV process, which would allow us to determine whether a group practice should have reported quality data codes for additional measures. In addition, the MAV will also allow us to determine whether a group practice should have reported on any of the cross-cutting measures specified in Table 52. The MAV process we will implement for claims and registry for the 2017 PQRS payment adjustment is the same process that was established for reporting periods occurring in 2014 for the 2014 PQRS

incentive. For more information on the claims MAV process, please visit http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2014_PQRS_Claims_MeasureApplicabilityValidation_12132013.zip. For more information on the registry MAV process, please visit http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2014_PQRS_Registry_MeasureApplicabilityValidation_12132013.zip.

For group practices comprised of 2–99 eligible professionals reporting for the 12-month reporting period for the 2017 PQRS payment adjustment via EHR: report 9 measures covering at least 3 domains. If the group practice’s CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

Please note that the discussion in this section III.K.4.b is limited to the criteria for the satisfactory reporting of group practices registered to participate in the GPRO for the 2017 PQRS payment adjustment using the EHR-based reporting mechanism to group practices comprised of 2–99 eligible professionals. The final criteria for group practices comprised of 100 or more eligible professionals are addressed in section III.K.1.c. following this section.

c. Criteria for Satisfactory Reporting on Individual PQRS Quality Measures for Group Practices Registered to Participate in the GPRO via a CMS-Certified Survey Vendor for the 2017 PQRS Payment Adjustment

In the CY 2014 PFS final rule with comment period, we introduced satisfactory reporting criterion for the 2014 PQRS incentive related to reporting the CG CAHPS survey measures via a CMS-certified survey vendor (see Table 49 at 78 FR 74486). Consistent with the criterion finalized for the 2014 PQRS incentive and the group practice reporting requirements under section 1848(m)(3)(C) of the Act, we proposed 3 options (of which a group practice would be able to select 1 out of the 3 options) for satisfactory reporting for the 2017 PQRS payment adjustment for group practices comprised of 25 or more eligible professionals (79 FR 40399).

Furthermore, as was required for group practices reporting via the GPRO web interface for the reporting periods

occurring in 2014 (78 FR 74485), we proposed that all group practices comprised of 100 or more eligible professionals that register to participate in the PQRS GPRO, regardless of the reporting mechanism the group practice chooses, would be required to select a CMS-certified survey vendor to administer the CAHPS for PQRS survey on their behalf. As such, for purposes of meeting the criteria for satisfactory reporting for the 2017 PQRS payment adjustment, a group practice participating in the PQRS GPRO would be required to use 1 of these 3 proposed reporting options mentioned above (that is, GPRO web interface, qualified registry or EHR). We noted that, for reporting periods occurring in 2014, we stated that we would administer and fund the collection of (CG-CAHPS) data for these groups (of 100 or more eligible professionals using the GPRO web interface that are required to report on CAHPS for PQRS survey measures) (78 FR 74452). We stated that we would bear the cost of administering the CAHPS for PQRS survey measures, as we were requiring the group practices to report on CAHPS for PQRS survey measures. Unfortunately, beginning in 2015, it will no longer be feasible for us to continue to bear the cost of group practices of 100 or more eligible professionals to report the CAHPS for PQRS survey measures. Therefore, the group practice would be required to bear the cost of administering the CAHPS for PQRS survey measures.

However, as CAHPS for PQRS was optional for group practices comprised of 25–99 eligible professionals in 2014 (78 FR 74485) and whereas we proposed to require reporting of CAHPS for PQRS for group practices comprised of 100 or more eligible professionals, we proposed that CAHPS for PQRS would be optional for groups of 25–99 and 2–24 eligible professionals. We noted that all group practices that would be required to report or voluntarily elect to report CAHPS for PQRS would need to select and pay a CMS-certified survey vendor to administer the CAHPS for PQRS survey on their behalf.

We invited public comment on these proposals related to our proposals to require reporting of CAHPS for PQRS for group practices comprised of 100 or more eligible professionals that register to participate in the PQRS GPRO as well as our proposal making the reporting of CAHPS for PQRS optional for group practices comprised of 2–99 eligible professionals that registry to participate in the PQRS GPRO to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment. The following is a summary of the comments

we received regarding on these proposals.

Comment: Commenters supported the option to report CAHPS for PQRS, as long as reporting CAHPS for PQRS remained optional. The majority of commenters opposed our proposal to require group practices comprised of 100 or more eligible professionals that register to participate in the PQRS GPRO, regardless of the reporting mechanism the group practice chooses, to select a CMS-certified survey vendor to administer the CAHPS for PQRS survey on their behalf. These commenters believe that this requirement was too burdensome, particularly because CMS is not bearing the cost of administering the survey. Some of these commenters requested that CMS delay requiring the reporting of CAHPS for PQRS to the 2016 reporting period. Other commenters requested that CMS continue to bear the cost of administering the CAHPS for PQRS survey.

Response: While we understand the commenters' concerns regarding requiring the reporting of CAHPS for PQRS, group practices comprised of 100 or more eligible professionals participating in the GPRO web interface reporting option have had 2 years of experience reporting CAHPS for PQRS as they have been required to report CAHPS for PQRS for both the 2013 and 2014 PQRS incentive. Groups of 25–99 eligible professionals reporting via GPRO web interface, qualified registry or EHR and groups of 100 or more eligible professionals reporting via qualified registry or EHR had the option to report CAHPS for PQRS in 2014. We believe that 2 years is enough time to become familiar with how the survey is administered. Therefore, we believe it is reasonable to require group practices of 100 or more eligible professionals to report on CAHPS for PQRS. With respect to some commenters' concerns about the additional burden the proposal to require group practices comprised of 100 or more eligible professionals that register to participate in the PQRS GPRO to report CAHPS for PQRS places on these group practices, we understand that this proposed requirement could bring additional reporting burden on these larger group practices. We believe that the value of the information contained in the CAHPS for PQRS survey outweighs this concern. In addition, we note that large group practices tend to be more sophisticated than other group practices with respect to resources, and, as such, we believe that this mitigates any additional burden on group practices of 100 or more eligible professionals.

Therefore, based on the reasons we state here and in the proposed rule, we are finalizing our proposal to require reporting of CAHPS for PQRS for group practices comprised of 100 or more eligible professionals that register to participate in the PQRS GPRO.

We are also finalizing our proposal to make the reporting of CAHPS for PQRS optional for group practices comprised of 2–99 eligible professionals that register to participate in the PQRS GPRO to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment.

Furthermore, we understand the commenters' concerns regarding having the group practices bear the cost of administering the CAHPS for PQRS survey, particularly for those group practices who will be required to report CAHPS for PQRS to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment. However, it is not feasible for us to continue to bear the cost of administering the CAHPS for PQRS survey. We believe that bearing the cost of the CAHPS for PQRS survey for 2013 and 2014 provided adequate time for group practices to become familiar with administering the CAHPS for PQRS survey as well as signaled our commitment to reporting of the CAHPS for PQRS survey into the future.

Because of the comments received, we are finalizing the following final criteria for satisfactory reporting for the 2017 PQRS payment adjustment for group practices comprised of 2 or more eligible professionals. The following options are voluntary ways to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment for groups comprised of 2–99 eligible professionals. However, group practices comprised of 100 or more eligible professionals that are registered to participate in the GPRO must select one of these options to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment.

Option 1—Registry: If a group practice of 2 or more eligible professionals chooses to use a qualified registry, in conjunction with reporting the CAHPS for PQRS survey measures, for the 12-month reporting period for the 2017 PQRS payment adjustment, the group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor, and report at least 6 additional measures, outside of CAHPS for PQRS, covering at least 2 of the NQS domains using the qualified registry. If less than 6 measures apply to the group practice, the group practice must report up to 5 measures. Of the additional measures that must be reported in conjunction

with reporting the CAHPS for PQRS survey measures, if any eligible professional in the group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice must report on at least 1 measure in the cross-cutting measure set specified in Table 52.

Consistent with the group practice reporting option solely using a qualified registry for the 2017 PQRS payment adjustment, we understand that there may be instances where a group practice may not have at least 6 measures applicable to a group practice's practice. In this instance, a group practice reporting on less than 6 measures would still be able to meet the satisfactory reporting criterion via registry if the group practice reports on as many measures as are applicable to the group practice's practice, including the measures in the cross-cutting measure set specified in Table 52. If a group practice reports on less than 6 individual measures using the qualified registry reporting mechanism in conjunction with a CMS-certified survey vendor to report CAHPS for PQRS, the group practice would be subject to the MAV process, which would allow us to determine whether a group practice should have reported quality data codes for additional measures and/or measures covering additional NQS domains. For more information on the registry MAV process, please visit http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2014_PQRS_Registry_MeasureApplicabilityValidation_12132013.zip.

Option 2—EHR: If a group practice of 2 or more eligible professionals chooses to use a direct EHR product that is CEHRT or EHR data submission vendor that is CEHRT in conjunction with reporting the CAHPS for PQRS survey measures, for the 12-month reporting period for the 2017 PQRS payment adjustment, the group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor, and report at least 6 additional measures, outside of CAHPS for PQRS, covering at least 2 of the NQS domains using the direct EHR product that is CEHRT or EHR data submission vendor product that is CEHRT. If less than 6 measures apply to the group practice, the group practice must report up to 5 measures. Of the additional 6 measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, a group practice would be required to report on at least 1 measure for which there is Medicare patient data.

Option 3—GPRO Web Interface: Alternatively, if a group practice of 25–99 eligible professionals chooses to use the GPRO web interface in conjunction with reporting the CAHPS for PQRS survey measures, for the 12-month reporting period for the 2017 PQRS payment adjustment, the group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report on all measures included in the GPRO web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. A group practice will be required to report on at least 1 measure for which there is Medicare patient data.

Tables 50 and 51 provide a summary of the final criteria for satisfactory reporting—or, in lieu of satisfactory reporting, satisfactory participation in a QCDR—for the 2017 PQRS payment adjustment for eligible professionals and group practices. As you can see below, there are a total of 5 individual reporting options and 9 group practice reporting options. Therefore, there are a total of 14 reporting options under the PQRS for purposes of meeting the criteria for satisfactory reporting—or, in lieu of satisfactory reporting, satisfactory participation in a QCDR—for the 2017 PQRS payment adjustment.

d. The Consumer Assessment of Healthcare Providers Surgical Care Survey (S-CAHPS)

In addition to CAHPS for PQRS, we received comments last year supporting the inclusion of the Consumer Assessment of Healthcare Providers Surgical Care Survey (S-CAHPS). The S-CAHPS expands on the CG-CAHPS by focusing on aspects of surgical quality, which are important from the patient's perspective and for which the patient is the best source of information. The survey asks patients to provide feedback on surgical care, surgeons, their staff, and anesthesia care. It assesses patients' experiences with surgical care in both the inpatient and outpatient settings by asking respondents about their experience before, during and after surgery. The commenters stated that the CG-CAHPS survey would not accurately reflect the care provided by single- or multispecialty surgical or anesthesia groups. The commenters noted that S-CAHPS has been tested by the same

standards as CG-CAHPS and follows the same collection mechanism as the CG-CAHPS. We agree with the commenters on the importance of allowing for the administration of S-CAHPS reporting and wish to allow for reporting of S-CAHPS in the PQRS for reporting mechanisms other than the QCDR. However, at this time, due to the cost and time it would take to find vendors to collect S-CAHPS data, it is not technically feasible to implement the reporting of the S-CAHPS survey measures for the 2017 PQRS payment adjustment. In the CY 2015 PFS proposed rule (79 FR 40400), we solicited comments on how to allow for reporting of the S-CAHPS survey measures for the 2018 PQRS payment adjustment and beyond. In addition, we sought comments on how to allow for reporting of the S-CAHPS survey measures for the 2018 PQRS payment adjustment and beyond. The following is a summary of the comments we received on these proposal:

Comment: The majority of commenters supported the introduction of S-CAHPS in the PQRS. These commenters supported our proposal to allow the reporting of S-CAHPS via a QCDR, and other commenters requested that group practices be able to report S-CAHPS via a CMS-certified survey vendor, similar to the way CAHPS for PQRS is currently being reported under the PQRS. Other commenters expressed concerns on introducing S-CAHPS for the PQRS. One commenter stated that S-CAHPS does not adequately capture the patient and caregiver experience with all types of anesthesia professionals. Another commenter expressed concerns related to determining how to select patients for which to administer S-CAHPS. Commenters were also concerned with the financial burden of administering the S-CAHPS survey, and asked CMS to explore ways to fund the administration of the S-CAHPS survey.

Response: We appreciate the commenters' feedback. However, at this time, due to the cost and time it would take to find vendors to collect S-CAHPS data, it is not technically feasible to implement the reporting of the S-CAHPS survey measures for the 2017 or 2018 PQRS payment adjustments. We note, however, that if a QCDR wishes to administer the S-CAHPS as a non-PQRS measure for the 2017 or 2018 PQRS payment adjustments, we would allow the QCDR to do so. We will take these comments into consideration as we continue to work to introduce S-CAHPS in the PQRS measure set for future years.

**TABLE 50: Summary of Requirements for the 2017 PQRS Payment Adjustment:
Individual Reporting Criteria for the Satisfactory Reporting of Quality Measures Data via Claims,
Qualified Registry, and EHRs and Satisfactory Participation Criterion in QCDRs**

Reporting Period	Measure Type	Reporting Mechanism	Satisfactory Reporting/Satisfactory Participation Criteria
12-month (Jan 1– Dec 31, 2015)	Individual Measures	Claims	Report at least 9 measures, covering at least 3 of the NQS domains AND report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the measures reported, if the eligible professional sees at least 1 Medicare patient in a face-to-face encounter, the eligible professional will report on at least 1 measure contained in the proposed cross-cutting measure set specified in Table 52. If less than 9 measures apply to the eligible professional, the eligible professional would report up to 8 measure(s), AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.
12-month (Jan 1– Dec 31, 2015)	Individual Measures	Qualified Registry	Report at least 9 measures, covering at least 3 of the NQS domains AND report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the measures reported, if the eligible professional sees at least 1 Medicare patient in a face-to-face encounter, the eligible professional will report on at least 1 measure contained in the proposed cross-cutting measure set specified in Table 52. If less than 9 measures apply to the eligible professional, the eligible professional would report up to 8 measure(s), AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.
12-month (Jan 1– Dec 31, 2015)	Individual Measures	Direct EHR Product or EHR Data Submission Vendor Product	Report 9 measures covering at least 3 of the NQS domains. If an eligible professional's direct EHR product or EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional would be required to report all of the measures for which there is Medicare patient data. An eligible professional would be required to report on at least 1 measure for which there is Medicare patient data.
12-month (Jan 1– Dec 31, 2015)	Measures Groups	Qualified Registry	Report at least 1 measures group AND report each measures group for at least 20 patients, the majority (11 patients) of which are required to be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.
12-month (Jan 1– Dec 31, 2015)	Individual PQRS measures and/or non-PQRS measures reportable via a QCDR	Qualified Clinical Data Registry (QCDR)	Report at least 9 measures available for reporting under a QCDR covering at least 3 of the NQS domains, AND report each measure for at least 50 percent of the eligible professional's patients. Of these measures, the eligible professional would report on at least 2 outcome measures, OR, if 2 outcomes measures are not available, report on at least 1 outcome measures and at least 1 of the following types of measures – resource use, patient experience of care, efficiency/appropriate use, or patient safety

TABLE 51: Summary of Requirements for the 2017 PQRS Payment Adjustment: Group Practice Reporting Criteria for Satisfactory Reporting of Quality Measures Data via the GPRO

Reporting Period	Group Practice Size	Measure Type	Reporting Mechanism	Satisfactory Reporting Criteria
12-month (Jan 1–Dec 31, 2015)	25-99 eligible professionals	Individual GPRO Measures in the GPRO Web Interface	GPRO Web Interface	Report on all measures included in the web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. In other words, we understand that, in some instances, the sampling methodology we provide will not be able to assign at least 248 patients on which a group practice may report, particularly those group practices on the smaller end of the range of 25–99 eligible professionals. If the group practice is assigned less than 248 Medicare beneficiaries, then the group practice must report on 100 percent of its assigned beneficiaries. A group practice must report on at least 1 measure for which there is Medicare patient data.
12-month (Jan 1–Dec 31, 2015)	25-99 eligible professionals and 100+ eligible professionals	Individual GPRO Measures in the GPRO Web Interface + CAHPS for PQRS	GPRO Web Interface + CMS-Certified Survey Vendor	The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report on all measures included in the GPRO web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. A group practice will be required to report on at least 1 measure for which there is Medicare patient data.
12-month (Jan 1–Dec 31, 2015)	2-99 eligible professionals	Individual Measures	Qualified Registry	Report at least 9 measures, covering at least 3 of the NQS domains. Of these measures, if a group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice would report on at least 1 measure in the cross-cutting measure set specified in Table 52. If less than 9 measures covering at least 3 NQS domains apply to the group practice, the group practice would report up to 8 measures covering 1–3 NQS domains for which there is Medicare patient data, AND report each measure for at least 50 percent of the group's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.
12-month (Jan 1–Dec 31, 2015)	2-99 eligible professionals and 100+ eligible professionals	Individual Measures + CAHPS for PQRS	Qualified Registry + CMS-Certified Survey Vendor	The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor, and report at least 6 additional measures, outside of CAHPS for PQRS, covering at least 2 of the NQS domains using the qualified registry. If less than 6 measures apply to the group practice, the group practice must report up to 5 measures. Of the

Reporting Period	Group Practice Size	Measure Type	Reporting Mechanism	Satisfactory Reporting Criteria
	nals			additional measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, if any eligible professional in the group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice must report on at least 1 measure in the cross-cutting measure set specified in Table 52.
12-month (Jan 1–Dec 31, 2015)	2-99 eligible professionals	Individual Measures	Direct EHR Product or EHR Data Submission Vendor Product	Report 9 measures covering at least 3 domains. If the group practice's direct EHR product or EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.
12-month (Jan 1–Dec 31, 2015)	2-99 eligible professionals and 100+ eligible professionals	Individual Measures + CAHPS for PQRS	Direct EHR Product or EHR Data Submission Vendor Product + CMS-Certified Survey Vendor	The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor, and report at least 6 additional measures, outside of CAHPS for PQRS, covering at least 2 of the NQS domains using the direct EHR product or EHR data submission vendor product. If less than 6 measures apply to the group practice, the group practice must report up to 5 measures. Of the additional 6 measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, a group practice would be required to report on at least 1 measure for which there is Medicare patient data.

5. Statutory Requirements and Other Considerations for the Selection of PQRS Quality Measures for Meeting the Criteria for Satisfactory Reporting for 2015 and Beyond for Individual Eligible Professionals and Group Practices

CMS undergoes an annual Call for Measures that solicits new measures from the public for possible inclusion in the PQRS. During the Call for Measures, we request measures for inclusion in PQRS that meet the following statutory and non-statutory criteria.

Sections 1848(k)(2)(C) and 1848(m)(3)(C)(i) of the Act, respectively, govern the quality measures reported by individual eligible professionals and group practices under the PQRS. Under section 1848(k)(2)(C)(i) of the Act, the PQRS quality measures shall be such measures selected by the Secretary from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act, which is currently the National Quality Forum (NQF). However, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the NQF, section 1848(k)(2)(C)(ii) of the Act authorizes the Secretary to specify a measure that is not so endorsed as long

as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary, such as the Ambulatory Quality Alliance (AQA). In light of these statutory requirements, we believe that, except in the circumstances specified in the statute, each PQRS quality measure must be endorsed by the NQF. Additionally, section 1848(k)(2)(D) of the Act requires that for each PQRS quality measure, “the Secretary shall ensure that eligible professionals have the opportunity to provide input during the development, endorsement, or selection of measures applicable to services they furnish.” The statutory requirements under section 1848(k)(2)(C) of the Act, subject to the exception noted previously, require only that the measures be selected from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act (that is, the NQF) and are silent as to how the measures that are submitted to the NQF for endorsement are developed.

The basic steps for developing measures applicable to physicians and other eligible professionals prior to submission of the measures for endorsement may be carried out by a variety of different organizations. We do

not believe there need to be special restrictions on the type or make-up of the organizations carrying out this basic process of development of physician measures, such as restricting the initial development to physician-controlled organizations. Any such restriction would unduly limit the basic development of quality measures and the scope and utility of measures that may be considered for endorsement as voluntary consensus standards for purposes of the PQRS.

In addition to section 1848(k)(2)(C) of the Act, section 1890A of the Act, which was added by section 3014(b) of the Affordable Care Act, requires that the Secretary establish a pre-rulemaking process under which certain steps occur with respect to the selection of certain categories of quality and efficiency measures, one of which is that the entity with a contract with the Secretary under section 1890(a) of the Act (that is, the NQF) convene multi-stakeholder groups to provide input to the Secretary on the selection of such measures. These categories are described in section 1890(b)(7)(B) of the Act, and include such measures as the quality measures selected for reporting under the PQRS. In accordance with section 1890A(a)(1) of the Act, the NQF convened multi-stakeholder groups by creating the

Measure Applications Partnership (MAP). Section 1890A(a)(2) of the Act requires that the Secretary must make publicly available by December 1st of each year a list of the quality and efficiency measures that the Secretary is considering for selection through rulemaking for use in the Medicare program. The NQF must provide CMS with the MAP's input on the selection of measures by February 1st of each year. The lists of measures under consideration for selection through rulemaking in 2014 are available at <http://www.qualityforum.org/map/>.

As we noted above, section 1848(k)(2)(C)(ii) of the Act provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). We may select measures under this exception if there is a specified area or medical topic for which a feasible and practical measure has not been endorsed by the entity, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Under this exception, aside from NQF endorsement, we requested that stakeholders apply the following considerations when submitting measures for possible inclusion in the PQRS measure set:

- Measures that are not duplicative of another existing or proposed measure.
- Measures that are further along in development than a measure concept.
- CMS is not accepting claims-based-only reporting measures in this process.
- Measures that are outcome-based are preferred to clinical process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnosis and therapeutics.
- Measures that identify care coordination and communication.
- Measures that identify care coordination of patient experience and patient-reported outcomes.
- Measures that address efficiency, cost and resource use.

As a general matter, please note that the measure tables contained in this section III.K. may also contain discussions of comments we received related to proposed changes to the measures included in the quality performance standard under the Shared Savings Program.

a. PQRS Quality Measures

Taking into consideration the statutory and non-statutory criteria we described previously, this section

contains our responses to our proposals related to the measures in the PQRS for 2015 and beyond. We classified all measures against six domains based on the NQS's six priorities, as follows:

(1) *Patient Safety*. These measures reflect the safe delivery of clinical services in all healthcare settings. These measures may address a structure or process that is designed to reduce risk in the delivery of healthcare or measure the occurrence of an untoward outcome such as adverse events and complications of procedures or other interventions.

(2) *Person and Caregiver-Centered Experience and Outcomes*. These are measures that reflect the potential to improve patient-centered care and the quality of care delivered to patients. They emphasize the importance of collecting patient-reported data and the ability to impact care at the individual patient level, as well as the population level. These are measures of organizational structures or processes that foster both the inclusion of persons and family members as active members of the health care team and collaborative partnerships with providers and provider organizations or can be measures of patient-reported experiences and outcomes that reflect greater involvement of patients and families in decision making, self-care, activation, and understanding of their health condition and its effective management.

(3) *Communication and care coordination*. These measures demonstrate appropriate and timely sharing of information and coordination of clinical and preventive services among health professionals in the care team and with patients, caregivers, and families to improve appropriate and timely patient and care team communication. They may also be measures that reflect outcomes of successful coordination of care.

(4) *Effective clinical care*. These are measures that reflect clinical care processes closely linked to outcomes based on evidence and practice guidelines or measures of patient-centered outcomes of disease states.

(5) *Community/population health*. These measures reflect the use of clinical and preventive services and achieve improvements in the health of the population served. They may be measures of processes focused on primary prevention of disease or general screening for early detection of disease unrelated to a current or prior condition.

(6) *Efficiency and cost reduction*. These measures reflect efforts to lower costs and to significantly improve

outcomes and reduce errors. These are measures of cost, resource use and appropriate use of healthcare resources or inefficiencies in healthcare delivery.

Please note that the PQRS quality measure specifications for any given PQRS individual quality measure may differ from specifications for the same quality measure used in prior years. For example, for the PQRS quality measures that were selected for reporting in 2014 and beyond, please note that detailed measure specifications, including the measure's title, for the individual PQRS quality measures for 2013 and beyond may have been updated or modified during the NQF endorsement process or for other reasons.

In addition, due to our desire to align measure titles with the measure titles that have been finalized for 2013, 2014, 2015, and potentially subsequent years of the EHR Incentive Program for Eligible Professionals, we note that the measure titles for measures available for reporting via EHR may change. To the extent that the EHR Incentive Program for Eligible Professionals updates its measure titles to include version numbers (77 FR 13744), we will use these version numbers to describe the PQRS EHR measures that will also be available for reporting for the EHR Incentive Program for Eligible Professionals. We will continue to work toward complete alignment of measure specifications across programs, whenever possible.

Through NQF's measure maintenance process, NQF-endorsed measures are sometimes updated to incorporate changes that we believe do not substantively change the nature of the measure. Examples of such changes could be updated diagnosis or procedure codes or changes to exclusions to the patient population or definitions. We believe these types of maintenance changes are distinct from substantive changes to measures that result in what are considered new or different measures. Further, we believe that non-substantive maintenance changes of this type do not trigger the same agency obligations under the Administrative Procedure Act.

In the CY 2013 PFS final rule with comment period, we finalized our proposal providing that if the NQF updates an endorsed measure that we have adopted for the PQRS in a manner that we consider to not substantively change the nature of the measure, we would use a subregulatory process to incorporate those updates to the measure specifications that apply to the program (77 FR 69207). We believe this adequately balances our need to incorporate non-substantive NQF

updates to NQF-endorsed measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We also noted that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process. We will revise the Specifications Manual and post notices to clearly identify the updates and provide links to where additional information on the updates can be found. Updates will also be available on the CMS PQRS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html>.

CMS is not the measure steward for most of the measures available for reporting under the PQRS. We rely on outside measure stewards and developers to maintain these measures. In Table 55, we proposed that certain measures be removed from the PQRS measure set due to the measure owner/developer indicating that it will not be able to maintain the measure. We noted that this proposal is contingent upon the measure owner/developer not being able to maintain the measure. Should we learn that a certain measure owner/developer is able to maintain the measure, or that another entity is able to maintain the measure in a manner that allows the measure to be available for reporting under the PQRS for the CY 2017 PQRS payment adjustment, we proposed to keep the measure available for reporting under the PQRS and therefore not finalize our proposal to remove the measure. In addition, if, after the display of this final rule with comment period, we discover additional measures within the current PQRS measure set that a measure owner/developer can no longer maintain, we proposed to remove these measures from reporting for the PQRS beginning in 2015. We will discuss any such instances in the PQRS measure tables below.

In addition, we noted that we have received feedback from stakeholders, particularly first-time participants who find it difficult to understand which measures are applicable to their particular practice. In an effort to aid eligible professionals and group practices to determine what measures best fit their practice, and in collaboration with specialty societies, we are beginning to group our final measures available for reporting according to specialty. The current listing of our measures by specialty can

be found on our Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html>. Please note that these groups of measures are meant to provide guidance to those eligible professionals seeking to determine what measures to report. Eligible professionals are not required to report measures according to these suggested groups of measures. In addition to group measures according to specialty, we also plan to have a measure subset for measures that specifically addresses multiple chronic conditions. As measures are adopted or revised, we will continue to update these groups to reflect the measures available under the PQRS, as well as add more specialties.

In the CY 2014 PFS final rule with comment period, we stated that “unless there are errors discovered in updated electronic measure specifications, the PQRS intends to use the most recent, updated versions of electronically specified clinical quality measures for that year” (78 FR 74489). We proposed that, if we discovered errors in the most recently updated electronic measure specifications for a certain measure, we would use the version of electronic measure specifications that immediately precedes the most recently updated electronic measure specifications. Any such change to a measure is also described in the PQRS measure tables below.

Additionally, we noted that, with respect to the following e-measure CMS140v2, Breast Cancer Hormonal Therapy for Stage IC–IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer (NQF 0387), a substantive error was discovered in the June 2013 version of this electronically specified clinical quality measure. Therefore, the PQRS required the use of the prior, December 2012 version of this measure, which is CMS140v1 (78 FR 74489). Please note that, consistent with other EHR measures, since a more recent and corrected version of this measure has been developed, we will require the reporting of the most recent, updated versions of the measure Breast Cancer Hormonal Therapy for Stage IC–IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer (NQF 0387)—currently version CMS140v3—for the year.

b. Cross-Cutting Measure Set for 2015 and Beyond

In accordance with our criteria for the satisfactory reporting of PQRS measures for the 2017 PQRS payment adjustment via claims and registry that requires an

eligible professional or group practice to report on at least 2 cross-cutting measures, we proposed 18 cross-cutting measure set specified in Table 21 in the CY 2015 PFS proposed rule for 2015 and beyond (79 FR 40404). Please note that we are finalizing all measures as proposed (see Table 52). We are also adding a measure to the list of cross-cutting measures, based on comments that were submitted. Please note that our response and final decision for each of these measures is found in Table 52. We have also indicated the PQRS reporting mechanism or mechanisms through which each measure could be submitted. Please note that we are changing some of the reporting mechanisms available for certain cross-cutting measures in Table 52 from the reporting options we proposed would be available in the CY 2015 PFS proposed rule (79 FR 40404). To the extent that changes to the reporting mechanisms for the cross-cutting measures specified in Table 52 were made from what was specified in the proposed rule, we provide the explanation and rationale for those changes in Table 53.

The following are high-level comments regarding our proposals related to the proposed cross-cutting measure set:

Comment: Several commenters supported the development of a cross-cutting measure set as well as the composition as proposed, while other commenters were concerned about this new requirement noting the measures may not be as applicable to some specialists.

Response: With respect to the commenters who expressed concern that the proposed measures in the proposed cross-cutting measures set did not apply to many specialties, we note that limitations such as only requiring reporting of a cross-cutting measures in a face-to-face encounter would exclude those eligible professionals for which the measures do not apply. With respect to taking a more phased-in approach to introducing the cross-cutting measure set, please note that we have modified this proposal to only require the reporting of 1 cross-cutting measure. We believe that requiring the reporting of 1 measure in the cross-cutting measures set is not overly burdensome and may help eligible professionals by providing direction on what measures to report. We are modifying our proposal to only require eligible professionals who see at least 1 Medicare patient in a face-to-face encounter to report on 1 cross-cutting measure.

TABLE 52: Individual Quality Cross-Cutting Measures for the PQRS to Be Available for Satisfactory Reporting Via Claims, Registry, and EHR Beginning in 2015

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description [†]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
Measures Finalized as Proposed or with Modifications											
N/A /402	N/ A	Communit y/Populati on Health	<p>Tobacco Use and Help with Quitting Among Adolescents: The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user</p> <p>Commenters agreed this measure was appropriately classified as cross-cutting. For this reason, CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2015 PQRS.</p>	NCQA / NCIQM			X			X	
N/A/ 400	N/ A	Effective Clinical Care	<p>Hepatitis C: One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk: Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis OR birthdate in the years 1945-1965 who received a one-time screening for HCV infection</p> <p>Commenters agreed this measure was appropriately classified as cross-cutting. For this reason, CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2015 PQRS.</p>	AGA / AASLD / AMA- PCPI			X				
0097 /046	N/ A	Communi cation and Care Coordinati on	<p>Medication Reconciliation: Percentage of patients aged 18 years and older discharged from any inpatient facility (for example, hospital, skilled nursing facility, or rehabilitation facility) and seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care who had a reconciliation of the discharge medications with the current medication list in the outpatient medical record documented</p> <p>This measure is reported as two rates stratified by age group:</p>	NCQA/ AMA- PCPI	X		X				

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GP/RO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			<p>Reporting Age Criteria 1: 18-64 years of age Reporting Age Criteria 2: 65 years and older.</p> <p>Commenters supported the inclusion of this measure as cross cutting “due to its focus on critical care coordination transitions between hospitals and ambulatory care providers.” As such, CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2015 PQRS. We note that while the proposed rule limited the applicability of this measure to patients 65 years and older, the range of this measure was changed to include patients 18-64 years of age by the measure steward. This measure update is endorsed by NQF.</p>								
0326 /047	N/ A	Communi- cation and Care Coordinati- on	<p>Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan</p> <p>Commenters agreed this measure was appropriately classified as cross-cutting. For this reason, CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2015 PQRS.</p>	NCQA/ AMA- PCPI	X		X			X	
0041 /110	147 v4	Communit- y/Populati- on Health	<p>Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization</p> <p>Commenters agreed this measure was appropriately classified as cross-cutting. For this reason, CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2015 PQRS.</p>	AMA- PCPI	X		X	X	X	X	ACO MU2
0043 /111	127 v3	Communit- y/Populati- on Health	<p>Pneumonia Vaccination Status for Older Adults: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine</p>	NCQA	X		X	X	X	X	ACO MU2

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GP/RO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			Commenters agreed this measure was appropriately classified as cross-cutting. For this reason, CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2015 PQRS.								
0421 /128	69v 3	Community/Population Health	<p>Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous six months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous six months of the current encounter</p> <p>Normal Parameters: Age 65 years and older BMI ≥ 23 and $< 30 \text{ kg/m}^2$; Age 18-64 years BMI ≥ 18.5 and $< 25 \text{ kg/m}^2$</p> <p>Commenters agreed this measure was appropriately classified as cross-cutting. For this reason, CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2015 PQRS.</p>	CMS/QIP	X		X	X	X	X	ACO MU2
0419 /130	68v 4	Patient Safety	<p>Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration</p> <p>Commenters agreed this measure was appropriately classified as cross-cutting. For this reason, CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2015 PQRS.</p>	CMS/QIP	X		X	X	X	X	ACO MU2
0420 /131	N/ A	Communication and Care Coordination	<p>Pain Assessment and Follow-Up: Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present</p>	CMS/QIP	X		X			X	

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			No comments were received regarding this measure being classified as cross-cutting. CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2015 PQRS.								
0418 /134	2v4	Community/Population Health	<p>Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan: Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen</p> <p>Commenters agreed this measure was appropriately classified as cross-cutting. For this reason, CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2015 PQRS.</p>	CMS/QIP	X		X	X	X	X	ACO MU2
N/A /182	N/A	Communication and Care Coordination	<p>Functional Outcome Assessment: Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies</p> <p>No comments were received regarding this measure being classified as cross-cutting. CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2015 PQRS.</p>	CMS/QIP	X		X				
0028 /226	138 v3	Community/Population Health	<p>Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user</p> <p>Commenters agreed this measure was appropriately classified as cross-cutting. For this reason, CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2015 PQRS.</p>	AMA-PCPI	X		X	X	X	X	ACO MU2 Million Hearts

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
0018 /236	165 v3	Effective Clinical Care	<p>Controlling High Blood Pressure: Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period</p> <p>Commenters agreed this measure was appropriately classified as cross-cutting. For this reason, CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2015 PQRS. This measure was part of the cardiovascular prevention and ischemic vascular disease measures group. Therefore, the details and rationale regarding the changes we are making to this measure can be found in our discussion of the cardiovascular prevention and ischemic vascular disease measures group in section III.K.5.d of this final rule.</p>	NCQA	X		X	X	X		ACO MU2 Million Hearts
0038 /240	117 v3	Communit y/Populati on Health	<p>Childhood Immunization Status: Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday</p> <p>Commenters agreed this measure was appropriately classified as cross-cutting. For this reason, CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2015 PQRS.</p>	NCQA				X			MU2

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
N/A /317	22v 3	Community/Population Health	<p>Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure (BP) AND a recommended follow-up plan is documented based on the current blood pressure reading as indicated</p> <p>Commenters agreed this measure was appropriately classified as cross-cutting. For this reason, CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2015 PQRS.</p>	CMS/QIP	X		X	X	X	X	ACO MU2 Million Hearts
0101 /318	139 v3	Patient Safety	<p>Falls: Screening for Fall Risk: Percentage of patients 65 years of age and older who were screened for future fall risk at least once during the measurement period</p> <p>Commenters agreed this measure was appropriately classified as cross-cutting. For this reason, CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2015 PQRS.</p>	NCQA				X	X		ACO MU2
0005 &00 06 /321	N/ A	Person and Caregiver Experience and Outcomes	<p>CAHPS for PQRS Clinician/Group Survey:</p> <ul style="list-style-type: none"> • Getting timely care, appointments, and information; • How well providers Communicate; • Patient's Rating of Provider; • Access to Specialists; • Health Promotion & Education; • Shared Decision Making; • Health Status/Functional Status; • Courteous and Helpful Office Staff; • Care Coordination; • Between Visit Communication; • Helping Your to Take Medication as Directed; and • Stewardship of Patient Resources <p>No comments were received regarding this measure being classified as cross-cutting. CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2015 PQRS.</p>	AHRQ		X					ACO

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
N/A /374	50v 3	Communi- cation and Care Coordinati- on	<p>Closing the Referral Loop: Receipt of Specialist Report: Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred</p> <p>No comments were received regarding this measure being classified as cross-cutting. CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2015 PQRS.</p>	CMS/BA H				X			MU2
Additional Measures Finalized in Response to Public Comment											
0059 /001	122 v3	Effective Clinical Care	<p>Diabetes: Hemoglobin A1c Poor Control: Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period</p> <p>This measure was not proposed for the cross-cutting measure set for 2015 and beyond. However, in addition to seeking comment on the proposed cross-cutting measure set specified in Table 21 of the proposed rule, we sought comment on other measures that commenters believed should be included in that proposed cross-cutting measure set for 2015 and beyond (79 FR 40403). Commenters suggested that CMS “include a diabetes-related measure such as NQF 0059 “Hemoglobin A1 C Poor Control” or other diabetes measure in the cross-cutting measure set for reporting under PQRS” as it is a measure that most eligible professionals can report. CMS agrees and is, therefore, finalizing the addition of PQRS #001 to the cross-cutting measure set for 2015 PQRS. CMS may consider additional measures for the cross-cutting measure set in future program years.</p>	NCQA	X		X	X	X	X	ACO MU2

¥ Measure details including titles, descriptions and measure owner information may vary during a particular program year. This is due to the timing of measure specification preparation and the measure versions used by the various reporting options/methods. Please refer to the measure specifications that apply for each of the reporting options/methods for specific measure details.

c. New PQRS Measures Available for Reporting for 2015 and Beyond

Table 22 in the CY 2015 PFS proposed rule (79 FR 40410) contained the additional measures we proposed to include in the PQRS measure set for CY 2015 and beyond. In Table 53, we

provide our response to the comments we received on these measures as well as our final decisions on these proposed measures. We have also indicated the PQRS reporting mechanism or mechanisms through which each measure could be submitted. As stated

above, please note that the following tables may also contain discussions of comments we received related to proposed changes to the measures included in the quality performance standard under the Shared Savings Program.

TABLE 53: New Individual Quality Measures and Those Included in Measures Groups for the PQRS to Be Available for Satisfactory Reporting Beginning in 2015

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GP/PRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
Measures Finalized as Proposed or with Modifications											
187 9 /38 3	N/ A	Patient Safety	<p>Adherence to Antipsychotic Medications for Individuals with Schizophrenia: The percentage of individuals 18 years of age or greater as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who are prescribed an antipsychotic medication, with adherence to the antipsychotic medication [defined as a Proportion of Days Covered (PDC)] of at least 0.8 during the measurement period (12 consecutive months)</p> <p>Commenters supported the inclusion of this measure in PQRS but request this measure also be reportable through claims. Although CMS understands commenters' concern regarding reporting via registry only, we have determined that the complexity of the measure warrants reportability only through the registry reporting option. For this reason, CMS is finalizing this measure to be reportable beginning in 2015 for PQRS.</p>	CMS / FMQAI			X				
N/ A /38 4	N/ A	Effective Clinical Care	<p>Adult Primary Rhegmatogenous Retinal Detachment Repair Success Rate: Percentage of surgeries for primary rhegmatogenous retinal detachment where the retina remains attached after only one surgery</p> <p>CMS received no comments on this measure. This is an outcome-based measure that addresses a new clinical concept not currently captured within PQRS and targets a specialty provider group, ophthalmologist, who are often underrepresented in the PQRS program. As such, this measure provides meaningful value for the PQRS program. For these reasons, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.</p>	American Associatio n of Eye and Ear Centers of Excellenc e			X				
N/ A /38 5	N/ A	Effective Clinical Care	<p>Adult Primary Rhegmatogenous Retinal Detachment Surgery Success Rate: Percentage of retinal detachment cases achieving flat retinas six months post-surgery</p> <p>Commenters disagreed with CMS's proposal to include this measure in PQRS, noting the measure has not been broadly</p>	American Associatio n of Eye and Ear Centers of Excellenc e/ The Australian Council			X				

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description [*]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			tested and possible unintended consequences that may drive physicians to perform retinal detachment surgeries in the hospital setting. This is an outcome-based measure that addresses a new clinical concept not currently captured within PQRS and targets a specialty provider group, ophthalmologists, who are often underrepresented in the PQRS program. Furthermore, the steward confirmed the setting of service is not relevant as a negative consequence of this measure. CMS agrees with this assessment that the setting of care is not an unintended consequence that would negatively impact the patient if this surgery were conducted in a hospital and believes this measure provides meaningful value for the PQRS program. For these reasons, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.	on Healthcar e Standards							
N/ A /38 6	N/ A	Person and Caregiver- Centered Experience and Outcomes	Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences: Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (for example, advance directives, invasive ventilation, hospice) at least once annually No comments were received regarding this measure being added to PQRS. CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.	AAN			X				
N/ A /38 7	N/ A	Effective Clinical Care	Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users: Percentage of patients regardless of age who are active injection drug users who received screening for HCV infection within the 12 month reporting period Although one commenter requested this measure be adjusted to include more than "injection drug use," citing its limiting risk factor, several commenters supported the inclusion of this measure in PQRS. Injection drug use has been associated as a high risk factor for HCV. Therefore, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.	AGA / AASLD / PCPI			X				
N/ A /38 8	N/ A	Patient Safety	Cataract Surgery with Intra-Operative Complications (Unplanned Rupture of Posterior Capsule Requiring Unplanned Vsitrectomy): Rupture of the posterior capsule during anterior segment surgery	AAEECE / ACHS			X			X	

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description*	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			<p>requiring vitrectomy</p> <p>Several commenters submitted positive comments about the inclusion of this measure in the PQRS program and requested that CMS make this measure reportable via claims. In addition, there were commenters that encouraged CMS to “test this measure before implementation.” Commenters did not specify the type of testing. This measure, per the guidelines of quality measure inclusion required for the PQRS program, has been tested by the steward. Furthermore, this is an outcome measure that complements the existing cataracts measures with a clinical focus not currently captured within PQRS. For these reasons, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS for registry and measure group reporting only. CMS is moving away from claims-based reporting and as such is not finalizing this measure for claims reporting in 2015 PQRS.</p>								
N/ A /38 9	N/ A	Effective Clinical Care	<p>Cataract Surgery: Difference Between Planned and Final Refraction: Percentage of patients who achieve planned refraction within ± 1.0 D</p> <p>Several commenters submitted positive comments about the inclusion of this measure in the PQRS program and requested that CMS make this measure reportable via claims. In addition, there were commenters that encouraged CMS to test this measure before implementation. Commenters did not specify the type of testing. This measure, per the guidelines of quality measure inclusion in the PQRS program, has been tested by the steward. Furthermore, this is an outcome measure that complements the existing cataracts measures with a clinical focus not currently captured within PQRS. For these reasons, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS for registry and measure group reporting only. CMS is moving away from the claims reporting option and as such is not finalizing this measure as reportable for claims in 2015 PQRS.</p>	AAEECE / ACHS			X			X	
N/ A /39 0	N/ A	Person and Caregiver- Centered Experience and	<p>Discussion and Shared Decision Making Surrounding Treatment Options: Percentage of patients aged 18 years and older with a diagnosis of hepatitis C with whom a physician or other qualified</p>	AGA / AASLD / PCPI			X			X	

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description*	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		Outcomes	<p>healthcare professional reviewed the range of treatment options appropriate to their genotype and demonstrated a shared decision making approach with the patient. To meet the measure, there must be documentation in the patient record of a discussion between the physician or other qualified healthcare professional and the patient that includes all of the following: treatment choices appropriate to genotype, risks and benefits, evidence of effectiveness, and patient preferences toward treatment</p> <p>Some commenters expressed concern that this measure might incentivize providers not to treat patients, indicating a provider might “simply note “the patient expressed reservations about potential side effects and we decided to defer treatment,” rather than working with the patient to address concerns and optimize uptake of the appropriate care.” However, CMS feels strongly that patients need to be provided appropriate information that would help patients to make their decision on treatment options. This measure focuses on discussion and shared decision making on treatment options. For these reasons, CMS is finalizing its proposal to include this measure for registry and measure group reporting in 2015 PQRS.</p>								
N/ A /39 1	N/ A	Communica tion and Care Coordination	<p>Follow-up After Hospitalization for Mental Illness (FUH): The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness diagnoses and who had an outpatient visit, an intensive outpatient encounter or partial hospitalization with a mental health practitioner. Two rates are reported:</p> <ul style="list-style-type: none"> - The percentage of discharges for which the patient received follow-up within 30 days of discharge - The percentage of discharges for which the patient received follow-up within 7 days of discharge <p>Commenters supported the inclusion of this measure in PQRS but request this measure also be reportable through claims. It is a priority for PQRS to ultimately increase the quality of health care. In order to achieve this goal, PQRS needs reliable and robust data on health service delivery and claims-based reporting has demonstrated, over</p>	NCQA			X				

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			several years, the highest error rate among the PQRS reporting options. For this reason, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS for registry reporting only.								
N/ A /39 2	N/ A	Patient Safety	HRS-12: Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation: Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation Commenters supported the inclusion of this measure in PQRS. For this reason, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.	HRS			X				
N/ A /39 3	N/ A	Patient Safety	HRS-9: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision: Infection rate following CIED device implantation, replacement, or revision Commenters supported the inclusion of this measure in PQRS. For this reason, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.	HRS			X				
140 7 /39 4	N/ A	Community/ Population Health	Immunizations for Adolescents: The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday Commenters supported the inclusion of this measure in PQRS. For this reason, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.	NCQA			X				
N/ A /39 5	N/ A	Communica tion and Care Coordination	Lung Cancer Reporting (Biopsy/Cytology Specimens): Pathology reports based on biopsy and/or cytology specimens with a diagnosis of primary nonsmall cell lung cancer classified into specific histologic type or classified as NSCLC-NOS with an explanation included in the pathology report Commenters supported the inclusion of this measure in PQRS. For this reason, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.	CAP	X		X				
N/ A /39 6	N/ A	Communica tion and Care Coordination	Lung Cancer Reporting (Resection Specimens): Pathology reports based on resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer, histologic type Commenters supported the inclusion of this	CAP	X		X				

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			measure in PQRS. For this reason, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.								
N/ A /39 7	N/ A	Communica tion and Care Coordination	<p>Melanoma Reporting: Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness and ulceration and for pT1, mitotic rate</p> <p>Commenters supported the inclusion of this measure in PQRS. For this reason, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.</p>	CAP	X		X				
N/ A /39 8	N/ A	Effective Clinical Care	<p>Optimal Asthma Control: Patients ages 5-50 (pediatrics ages 5-17) whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools</p> <p>Several commenters disagreed with CMS's proposal to replace existing measure (PQRS #064 "Asthma: Assessment of Asthma Control – Ambulatory Care Setting") with this new measure. Details regarding commenters concerns with removing PQRS #064 can be found in Table 56. Although CMS understands the limitations of the current measure as it relates to the upper age limit, risk adjustment and the calculation of improvement over time, this measure represents a more robust clinical outcome for asthma care. For this reason, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS for registry only.</p> <p>In addition, CMS re-evaluated the categorization of this measure to the Person and Caregiver Experience and Outcomes domain and determined it was more appropriately categorized under Effective Clinical Care. As such, CMS is finalizing this measure under Effective Clinical Care for 2015 PQRS program.</p>	MNCM			X				
N/ A /39 9	N/ A	Effective Clinical Care	<p>Post-Procedural Optimal Medical Therapy Composite (Percutaneous Coronary Intervention): Percentage of patients aged 18 years and older for whom PCI is performed who are prescribed optimal medical therapy at discharge</p> <p>Commenters supported the inclusion of this measure in PQRS. For this reason, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.</p>	ACC-AHA			X				

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
N/ A/ /40 0	N/ A	Effective Clinical Care	<p>Hepatitis C: One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk: Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis OR birthdate in the years 1945-1965 who received a one-time screening for HCV infection</p> <p>Although one commenter requested this measure be adjusted to include more than “injection drug use,” citing its limiting risk factor, injection drug use has been associated as a high-risk factor for HCV. Additionally, the commenter suggested that this measure include “risk groups” to encompass men who have sex with men (MSM). Transmission of HCV by sex is low and does not necessitate routine screening. Furthermore, several commenters supported the inclusion of this measure in PQRS. CMS received public comment from the measure steward indicating this measure should be classified under the domain of Effective Clinical Care. After further review, CMS determined this measure was more appropriately categorized under the Effective Clinical Care domain based on the HHS decision rule guidelines for categorizing measures. For these reasons, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.</p>	AGA / AASLD / AMA- PCPI			X				
N/ A/ /40 1	N/ A	Effective Clinical Care	<p>Screening for Hepatocellular Carcinoma (HCC) in patients with Hepatitis C Cirrhosis: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12 month reporting period</p> <p>Commenters supported the inclusion of this measure in PQRS, but also suggested CMS refine the measure language to include other risk groups and diagnosis. We appreciate the commenters’ support for this measure. With respect to the measure language, we note that we have decided not to make changes to this measure in order to maintain consistency with the specifications maintained by the measure</p>	AGA / AASLD / AMA- PCPI			X			X	

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			developer and owner. Based on the comments received, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.								
N/ A /40 2	N/ A	Community/ Population Health	<p>Tobacco Use and Help with Quitting Among Adolescents: The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user</p> <p>Commenters supported the inclusion of this measure in PQRS. For this reason, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.</p>	NCQA / NCIQM			X			X	
Measures Not Finalized as Proposed											
188 0 /N/ A	N/ A	Patient Safety	<p>Adherence to Mood Stabilizers for Individuals with Bipolar I Disorder: The measure calculates the percentage of individuals aged 18 years and older with bipolar I disorder who are prescribed a mood stabilizer medication, with adherence to the mood stabilizer medication [defined as a Proportion of Days Covered (PDC)] of at least 0.8 during the measurement period (12 consecutive months)</p> <p>Commenters supported the inclusion of this measure in PQRS but request this measure also be reportable through registry. CMS confirmed with the measure steward that this measure was tested for reportability through claims and not registry. Given this, CMS does not believe this measure is ready for implementation in 2015 PQRS as CMS does not believe this measure is appropriate for claims-based reporting and thus CMS is not finalizing this measure for reporting in 2015 PQRS.</p>	CMS/FM QAI	X						
N/ A /N/ A	N/ A	Person and Caregiver- Centered Experience and Outcomes	<p>Average change in functional status following lumbar spine fusion surgery: Average change from pre-operative functional status assessment to one year (nine to fifteen months) post-operative functional status using the Oswestry Disability Index (ODI version 2.1a) patient reported outcome tool</p> <p>Commenters note this measure has not been fully vetted or tested. Furthermore, there are analytic challenges to implementing this measure and the lack of a performance target to assess this measure against. For this reason, CMS is not finalizing this measure for inclusion in 2015 PQRS.</p>	MNCM			X				

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description*	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
N/ A /N/ A	N/ A	Efficiency and Cost Reduction	<p>Avoidance of inappropriate use of imaging for adult ED patients with traumatic low back pain: Avoidance of inappropriate use of imaging for adult ED patients with traumatic low back pain</p> <p>While one commenter supported the addition of this measure to PQRS noting it “will incentivize providers to minimize unnecessary or excessive radiation exposure, which insures to the benefit of beneficiaries,” the measure steward withdrew support of this measure as the measure is not yet sufficiently specified nor has it undergone public review and comment. For this reason, CMS is not finalizing this measure for PQRS 2015.</p>	ACEP			X				
188 5 /N/ A	N/ A	Person and Caregiver- Centered Experience and Outcomes	<p>Depression Response at Twelve Months-Progress Towards Remission: Adult patients age 18 and older with major depression or dysthymia and an initial PHQ-9 (Patient Health Questionnaire 9) score greater than nine who demonstrate a response to treatment at twelve months defined as a PHQ-9 score that is reduced by 50% or greater from the initial PHQ-9 score. This measure applies to both patients with newly diagnosed or existing depression identified during the defined measurement period whose current PHQ-9 score indicates a need for treatment</p> <p>CMS believes that NQF 1885 is duplicative of PQRS 370 “Depression Remission at Twelve Months.” As such, CMS is not finalizing its proposal to add NQF 1885 as a new measure for reporting in the 2015 PQRS Program.</p>	MNCM			X				
N/ A /N/ A	N/ A	Patient Safety	<p>Discontinuation of Antiviral Therapy for Inadequate Viral Response: Percentage of patients aged 18 years and older with a diagnosis of hepatitis C genotype 1 who had an inadequate response to antiviral treatment for whom antiviral treatment was discontinued</p> <p>Commenters, including the measure steward, suggest clinical guidelines are changing for Hepatitis C virus therapy, impacting the clinical appropriateness of this measure specifically. No other measures under consideration were affected. As such, CMS is not finalizing this measure for PQRS 2015, allowing time for the evolving clinical guidance to be finalized.</p>	AGA / AASLD / PCPI			X				

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description*	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
N/ A /N/ A	N/ A	Effective Clinical Care	<p>Freedom from Reintervention or Amputation Following Endovascular Infringuinal Lower Extremity Revascularization for Non-limb threatening ischemia: Percentage of patients undergoing endovascular infringuinal revascularization for non-limb threatening ischemia (claudication or asymptomatic) who do not require ipsilateral repeat revascularization or any amputation within one year</p> <p>The measure steward withdrew support of this measure as the measure specifications are incomplete at this time. For this reason, CMS is not finalizing this measure for PQRS 2015 but may consider this measure for a future program year.</p>	SVS			X				
N/ A /N/ A	N/ A	Effective Clinical Care	<p>Freedom from Reintervention or Amputation Following Open Infringuinal Lower Extremity Revascularization for non-limb threatening ischemia: Percentage of patients undergoing open infringuinal revascularization for non-limb threatening ischemia (claudication or asymptomatic) who do not require ipsilateral repeat revascularization or any amputation within one year</p> <p>The measure steward withdrew support of this measure as the measure specifications are incomplete at this time. For this reason, CMS is not finalizing this measure for PQRS 2015 but may consider this measure for a future program year.</p>	SVS			X				
662 /N/ A	N/ A	Communica tion and Care Coordination	<p>Median Time to Pain Management for Long Bone Fracture: Median time from emergency department (ED) arrival to time of initial oral, intranasal or parenteral pain medication administration for emergency department patients with a principal diagnosis of long bone fracture (LBF)</p> <p>While some commenters supported the inclusion of this measure in PQRS, after further review CMS determined that comparison across measurement periods, particularly when the reporting period for the PQRS payment adjustments is a 12-month calendar year, poses an analytic challenge for reporting purposes. CMS currently does not have a measure in the PQRS where data is collected outside a respective reporting period and compared to an existing reporting period without an</p>	CMS/OF MQ			X				

NQE/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			established performance met target. While we welcome intermediate outcome measures such as these, it is not technically feasible at this time to include this measure in the PQRS. For this reason, CMS is not finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.								

[¥] Measure details including titles, descriptions and measure owner information may vary during a particular program year. This is due to the timing of measure specification preparation and the measure versions used by the various reporting options/methods. Please refer to the measure specifications that apply for each of the reporting options/methods for specific measure details.

In Table 54, we provide our responses and final decisions on the measures for which we proposed a NQS domain change for reporting under the PQRS (79 FR 40419). Please note that we received comments regarding the process for changing a measure's domain. With respect to these comments, we appreciate the commenters' suggestions

regarding the process for domain changes for measures and will take these comments under consideration. We are developing guidelines for assigning measure domains and will use these guidelines to assign each measure in the PQRS program to a NQS domain when measure stewards submit measures through the Call for Measures

process each program year. We value feedback from measure developers and are dedicated to making updates to the PQRS program a transparent and collaborative process as it works to establish measures that are applicable to various domain categories.

TABLE 54: NQS Domain Changes for Individual Quality Measures and Those Included in Measures Groups for the PQRS Beginning in 2015

NQF/ PQRS	CMS E-Measure ID	NQS Domain 2014	NQS Domain 2015	Measure Title and Description	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
Measures Finalized as Proposed											
009 7/0 46	N/ A	Patient Safety	Communi- cation and Care Coordina- tion	<p>Medication Reconciliation: Percentage of patients aged 18 years and older discharged from any inpatient facility (for example, hospital, skilled nursing facility, or rehabilitation facility) and seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care who had a reconciliation of the discharge medications with the current medication list in the outpatient medical record documented.</p> <p>This measure is reported as two rates stratified by age group:</p> <p>Reporting Age Criteria 1: 18-64 years of age Reporting Age Criteria 2: 65 years and older.</p> <p>Commenters supported the proposed domain change for PQRS #46 from Patient Safety to Communication and Care Coordination. For this reason, CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.</p>	X		X				
065 0/1 37	N/ A	Effective Clinical Care	Communi- cation and Care Coordina- tion	<p>Melanoma: Continuity of Care – Recall System: Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12 month period, into a recall system that includes:</p> <ul style="list-style-type: none"> • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment <p>Commenters supported the proposed domain change for PQRS #137 from Effective Clinical Care to Communication and Care Coordination. For this reason, CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.</p>			X				
N/ A/2 88	N/ A	Effective Clinical Care	Communi- cation and Care Coordina- tion	<p>Dementia: Caregiver Education and Support: Percentage of patients, regardless of age, with a diagnosis of dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND referred to additional sources for support within a 12 month period</p> <p>Commenters disagreed with the proposed domain change but did not explain why. However, while this measure does fall into both the Communication and Care Coordination and Person and Caregiver-Centered</p>						X	

NQF/ PQRS	CMS E-Measure ID	NQS Domain 2014	NQS Domain 2015	Measure Title and Description	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
				Experience and Outcomes domains, Communication and Care Coordination should become the new primary domain. While the measure does target the education and referral of the patient's caregiver to supportive services, this is a secondary goal of the measure -- the primary intent is to disseminate information related to caring for a patient with dementia, including making connections to all potentially necessary providers. For these reasons, CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.							
N/ A/2 93	N/ A	Effective Clinical Care	Communi- cation and Care Coordina- tion	<p>Parkinson's Disease: Rehabilitative Therapy Options: All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (for example, physical, occupational, or speech therapy) discussed at least annually</p> <p>No comments were received regarding the domain for this measure. CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.</p>						X	
N/ A/2 94	N/ A	Effective Clinical Care	Communi- cation and Care Coordina- tion	<p>Parkinson's Disease: Parkinson's Disease Medical and Surgical Treatment Options Reviewed: All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate) who had the Parkinson's disease treatment options (for example, non-pharmacological treatment, pharmacological treatment, or surgical treatment) reviewed at least once annually</p> <p>No comments were received regarding the domain for this measure. CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.</p>						X	
N/ A/3 25	N/ A	Effective Clinical Care	Communi- cation and Care Coordina- tion	<p>Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions: Percentage of medical records of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) and a specific diagnosed comorbid condition (diabetes, coronary artery disease, ischemic stroke, intracranial hemorrhage, chronic kidney disease [stages 4 or 5], End Stage Renal Disease [ESRD] or congestive heart failure) being treated by another clinician with communication to the clinician treating the comorbid condition</p> <p>Commenters supported the proposed domain change for PQRS #325 from Effective Clinical Care to Communication and Care Coordination. For this reason, CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.</p>			X				
N/ A/3 03	N/ A	Effective Clinical Care	Person and Caregiver-	<p>Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery: Percentage of patients aged 18 years and older in sample who had cataract surgery and had</p>			X			X	

NQF/ PQRS	CMS E-Measure ID	NQS Domain 2014	NQS Domain 2015	Measure Title and Description	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			Centered Experience and Outcomes	improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey No comments were received regarding the domain for this measure. CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.							
N/ A/3 31	N/ A	Effective Clinical Care	Efficiency and Cost Reduction	Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Appropriate Use): Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 7 days of diagnosis or within 10 days after onset of symptoms Commenters supported the proposed domain change for PQRS #331 from Effective Clinical Care to Efficiency and Cost Reduction. For this reason, CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.			X			X	
N/ A/3 32	N/ A	Effective Clinical Care	Efficiency and Cost Reduction	Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use): Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulante, as a first line antibiotic at the time of diagnosis Commenters supported the proposed domain change for PQRS #332 from Effective Clinical Care to Efficiency and Cost Reduction. For this reason, CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.			X			X	
N/ A/3 47	N/ A	Effective Clinical Care	Patient Safety	Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) Who Die While in Hospital: Percent of patients undergoing endovascular repair of small or moderate abdominal aortic aneurysms (AAA) who die while in the hospital No comments were received regarding the domain for this measure. CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.			X				
N/ A/3 48	N/ A	Effective Clinical Care	Patient Safety	HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate: Patients with physician-specific risk-standardized rates of procedural complications following the first time implantation of an ICD No comments were received regarding the domain for this measure. CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.			X				
N/ A/3 54	N/ A	Effective Clinical Care	Patient Safety	Anastomotic Leak Intervention: Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass						X	

NQF/ PQRS	CMS E-Measure ID	NQS Domain 2014	NQS Domain 2015	Measure Title and Description	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
				or colectomy surgery No comments were received regarding the domain for this measure. CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.							
N/ A/3 55	N/ A	Effective Clinical Care	Patient Safety	Unplanned Reoperation within the 30 Day Postoperative Period: Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period No comments were received regarding the domain for this measure. CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.						X	
004 3 /11 1	12 7v 3	Effective Clinical Care	Commun ity/Popul ation Health	Pneumonia Vaccination Status for Older Adults: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine No comments were received regarding the domain for this measure. CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.	X		X	X	X	X	ACO MU2
032 1/0 82	N/ A	Commun ication and Care Coordina tion	Effective Clinical Care	Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute: Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving peritoneal dialysis who have a total Kt/V ≥ 1.7 per week measured once every 4 months Commenters supported the proposed domain change for PQRS #82 from Communication and Care Coordination to Effective Clinical Care. For this reason, CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.			X				
N/ A/1 80	N/ A	Commun ication and Care Coordina tion	Effective Clinical Care	Rheumatoid Arthritis (RA): Glucocorticoid Management: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months Commenters supported the proposed domain change for PQRS #180 from Communication and Care Coordination to Effective Clinical Care. For this reason, CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.						X	AQA
N/ A/2 80	N/ A	Commun ication and Care Coordina tion	Effective Clinical Care	Dementia: Staging of Dementia: Percentage of patients, regardless of age, with a diagnosis of dementia whose severity of dementia was classified as mild, moderate or severe at least once within a 12 month period Commenters supported the proposed domain change						X	

NQF/ PQRS	CMS E-Measure ID	NQS Domain 2014	NQS Domain 2015	Measure Title and Description	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
				for PQRS #280 from Communication and Care Coordination to Effective Clinical Care. For this reason, CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.							
065 4/0 93	N/ A	Communication and Care Coordination	Efficiency and Cost Reduction	<p>Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use: Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy</p> <p>Commenters supported the proposed domain change for PQRS #93 from Communication and Care Coordination to Efficiency and Cost Reduction. For this reason, CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.</p>	X		X			X	
N/ A/2 58	N/ A	Communication and Care Coordination	Patient Safety	<p>Rate of Open Repair of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7): Percent of patients undergoing open repair of small or moderate sized non-ruptured abdominal aortic aneurysms who do not experience a major complication (discharge to home no later than post-operative day #7)</p> <p>No comments were received regarding the domain for this measure. CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.</p>			X				
N/ A/2 59	N/ A	Communication and Care Coordination	Patient Safety	<p>Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #2): Percent of patients undergoing endovascular repair of small or moderate non-ruptured abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2)</p> <p>No comments were received regarding the domain for this measure. CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.</p>			X				
N/ A/2 60	N/ A	Communication and Care Coordination	Patient Safety	<p>Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2): Percent of asymptomatic patients undergoing CEA who are discharged to home no later than post-operative day #2</p> <p>No comments were received regarding the domain for this measure. CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.</p>			X				
152 5/3 26	N/ A	Patient Safety	Effective Clinical Care	Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy: Percentage of patients aged 18 years and older with a diagnosis of nonvalvular	X		X				

NQF/ PQRS	CMS E-Measure ID	NQS Domain 2014	NQS Domain 2015	Measure Title and Description	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
				<p>atrial fibrillation (AF) or atrial flutter whose assessment of the specified thromboembolic risk factors indicate one or more high-risk factors or more than one moderate risk factor, as determined by CHADS2 risk stratification, who are prescribed warfarin OR another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism</p> <p>One commenter agreed while another commenter disagreed with the proposal to change the domain of PQRS #326 from Patient Safety to Effective Clinical Care noting “providing anticoagulation therapy for atrial fibrillation and atrial flutter patients is a means of reducing the risk of stroke in patients presenting for more high- or moderate-risk factors.” While not using warfarin or another anticoagulation therapy is "a means of reducing the risk of stroke in patients presenting for more high- or moderate-risk factors," this is a secondary outcome of providing the medication, not a direct risk caused by the delivery of care. So, while taking warfarin or another anticoagulant may provide protection against stroke, it is not the primary intent of the measure. For these reasons, CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.</p>							
N/ A/3 21	N/ A	Communication and Care Coordination	Person and Caregiver Experience and Outcomes	<p>CAHPS for PQRS Clinician/Group Survey:</p> <ul style="list-style-type: none">• Getting timely care, appointments, and information;• How well providers Communicate;• Patient’s Rating of Provider;• Access to Specialists;• Health Promotion & Education;• Shared Decision Making;• Health Status/Functional Status;• Courteous and Helpful Office Staff;• Care Coordination;• Between Visit Communication;• Helping Your to Take Medication as Directed; and• Stewardship of Patient Resources <p>No comments were received regarding the domain for this measure. CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.</p>		X					ACO
Measures Not Finalized as Proposed											
N/ A/3 56	N/ A	Effective Clinical Care	Communication and Care Coordination	<p>Unplanned Hospital Readmission within 30 Days of Principal Procedure: Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure</p> <p>One commenter disagreed with CMS’ proposal to change the domain of this measure noting that "unplanned readmissions can be the result of many factors which extend well beyond communication and care coordination." The commenter suggested keeping</p>							X

NQF/ PQRS	CMS E-Measure ID	NQS Domain 2014	NQS Domain 2015	Measure Title and Description	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
				Effective Clinical Care as the NQS domain. CMS agreed with the commenter and is not finalizing its proposal to change the domain of PQRS #356 from Effective Clinical Care to Communication and Care Coordination for 2015 PQRS. This measure will remain as Effective Clinical Care in the 2015 PQRS measure set.							

¥ Measure details including titles, descriptions and measure owner information may vary during a particular program year. This is due to the timing of measure specification preparation and the measure versions used by the various reporting options/methods. Please refer to the measure specifications that apply for each of the reporting options/methods for specific measure details.

In Table 55, we provide the responses and final decisions related to the measures we proposed to remove from reporting under the PQRS (79 FR 40426).

TABLE 55: Measures Being Removed from the Existing PQRS Measure Set Beginning in 2015

NQF/ PQRS	NQS Domain	Measure Title and Description [†]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
Measures Finalized as Proposed										
0270/020	Patient Safety	<p>Perioperative Care: Timing of Prophylactic Parenteral Antibiotic – Ordering Physician: Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics, who have an order for prophylactic parenteral antibiotic to be given within one hour (if fluoroquinolone or vancomycin, 2 hours), prior to the surgical incision (or start of procedure when no incision is required)</p> <p>Some commenters disagreed with CMS’ proposal to remove this measure noting “disparate practice patterns among clinicians when selecting the more appropriate prophylactic antibiotic.” However, other commenters agreed with CMS’ proposal to remove this measure given the measure’s “emphasis on administration rather than ordering of antibiotics.” For this reason and given the measure’s high rate of performance in previous reporting years, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>	AMA- PCPI NCQA	X		X			X	
0092/028	Effective Clinical Care	<p>Aspirin at Arrival for Acute Myocardial Infarction (AMI): Percentage of patients, regardless of age, with an emergency department discharge diagnosis of acute myocardial infarction (AMI) who had documentation of receiving aspirin within 24 hours before emergency department arrival or during emergency department stay</p> <p>Commenters disagreed with CMS’ proposal to remove this measure noting it presents a “reporting opportunity for emergency physicians” which could create a reporting gap for that segment of providers reporting to PQRS. However, CMS continues to believe this measure represents a clinical concept that has been substantially adopted for initial treatment of patients suffering from acute myocardial infarction when clinically indicated. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>	AMA- PCPI NCQA	X		X				
0269/030	Patient Safety	<p>Perioperative Care: Timing of Prophylactic Antibiotic—Administering Physician: Percentage of surgical patients aged 18 years and older who receive an anesthetic when undergoing procedures</p>	AAO	X		X				

NQE/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		<p>with the indications for prophylactic parenteral antibiotics for whom administration of a prophylactic parenteral antibiotic ordered has been initiated within 1 hour (if fluoroquinolone or vancomycin, 2 hours) prior to the surgical incision (or start of procedure when no incision is required)</p> <p>Commenters disagreed with CMS' proposal to remove this measure noting "it is premature to remove a measure based on a high-performance rate when the EP reporting rate within the PQRS program is low." With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represents a clinical performance gap that should be measured by the PQRS Program. Additionally, CMS will apply the Measure Applicability Validation (MAV) process for claims-based reporting in those cases where specialists do not have enough relevant measures to report. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>								
0240/031	Effective Clinical Care	<p>Stroke and Stroke Rehabilitation: Venous Thromboembolism (VTE) Prophylaxis for Ischemic Stroke or Intracranial Hemorrhage: Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or intracranial hemorrhage who were administered venous thromboembolism (VTE) prophylaxis the day of or the day after hospital admission</p> <p>Commenters disagreed with CMS' proposal to remove this measure. Commenters maintain that these clinical concepts are appropriate for measurement at the individual physician level in addition to the facility level to help ensure the continuous care of stroke patients. CMS believes this measure represents a basic standard of care and does not add clinical value to PQRS at this time. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>	AANI	X		X				
0243/035	Effective Clinical Care	<p>Stroke and Stroke Rehabilitation: Screening for Dysphagia: Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or intracranial hemorrhage who receive any food, fluids or medication by mouth (PO) for whom a dysphagia screening was performed prior to PO intake in accordance with a dysphagia screening tool approved by the institution in</p>	AANI	X		X				

NQE/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		<p>which the patient is receiving care</p> <p>Commenters disagreed with CMS' proposal to remove this measure as they maintain that these clinical concepts are appropriate for measurement at the individual physician level in addition to the facility level to help ensure the continuous care of stroke patients. CMS continues to believe this measure represents a basic standard of care and does not add clinical value to PQRS at this time. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>								
0244/036	Effective Clinical Care	<p>Stroke and Stroke Rehabilitation: Rehabilitation Services Ordered: Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or intracranial hemorrhage for whom occupational, physical, or speech rehabilitation services were ordered at or prior to inpatient discharge OR documentation that no rehabilitation services are indicated at or prior to inpatient discharge</p> <p>Commenters disagreed with CMS' proposal to remove this measure as they maintain that these clinical concepts are appropriate for measurement at the individual physician level in addition to the facility level to help ensure the continuous care of stroke patients. CMS continues to believe this measure represents a basic standard of care and does not add clinical value to PQRS at this time. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>	AANI	X		X				
0637/045	Patient Safety	<p>Perioperative Care: Discontinuation of Prophylactic Parenteral Antibiotics (Cardiac Procedures): Percentage of cardiac surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics AND who received a prophylactic parenteral antibiotic, who have an order for discontinuation of prophylactic parenteral antibiotics within 48 hours of surgical end time</p> <p>Commenters disagreed with CMS' proposal to remove this measure, noting "it is premature to remove a measure based on a high-performance rate when the EP reporting rate within the PQRS program is low." With a performance rate above 90 percent for multiple consecutive years,</p>	AMA- PCPI NCQA	X		X				

NQE/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.								
0099/049	Effective Clinical Care	<p>Urinary Incontinence: Characterization of Urinary Incontinence in Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence whose urinary incontinence was characterized at least once within 12 months</p> <p>Commenters disagreed with removal of this measure due to high performance rates indicating this is not a good enough reason to remove a measure from the program. With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. For this reason, CMS is finalizing its proposal to remove this measure from 2015 PQRS.</p>	NCQA/ AMA- PCPI	X		X				
0093 /055	Effective Clinical Care	<p>Emergency Medicine: 12-Lead Electrocardiogram (ECG) Performed for Syncope: Percentage of patients aged 60 years and older with an emergency department discharge diagnosis of syncope who had a 12-lead electrocardiogram (ECG) performed</p> <p>Commenters disagreed with CMS' proposal to remove this measure, noting "it is premature to remove a measure based on a high-performance rate when the EP reporting rate within the PQRS program is low." With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. For this reason, CMS is finalizing its proposal to remove this measure from</p>	AMA- PCPI /NCQA	X		X				

NQF/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		reporting in 2015 PQRS.								
0232 /056	Effective Clinical Care	<p>Emergency Medicine: Community-Acquired Bacterial Pneumonia (CAP): Vital Signs: Percentage of patients aged 18 years and older with a diagnosis of community-acquired bacterial pneumonia (CAP) with vital signs documented and reviewed</p> <p>Commenters disagreed with CMS' proposal to remove this measure noting "it is premature to remove a measure based on a high-performance rate when the EP reporting rate within the PQRS program is low." With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>	AMA- PCPI /NCQA	X		X				
0096 /059	Effective Clinical Care	<p>Emergency Medicine: Community-Acquired Bacterial Pneumonia (CAP): Empiric Antibiotic: Percentage of patients aged 18 years and older with a diagnosis of community-acquired bacterial pneumonia (CAP) with an appropriate empiric antibiotic prescribed</p> <p>Commenters disagreed with CMS' proposal to remove this measure noting "it is premature to remove a measure based on a high-performance rate when the EP reporting rate within the PQRS program is low." With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>	AMA- PCPI /NCQA	X		X				
0001/064	Effective Clinical Care	<p>Asthma: Assessment of Asthma Control – Ambulatory Care Setting: Percentage of patients aged 5 through 64 years with a diagnosis of asthma who were evaluated at least once during the measurement period</p>	AMA- PCPI NCQA			X			X	

NQE/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		<p>for asthma control (comprising asthma impairment and asthma risk)</p> <p>Some commenters disagreed with the removal of this measure noting “this [assessment] is essential in order to ensure appropriate treatment for asthma which currently is less than optimal.” However, other commenters supported the removal of this measure. CMS continues to believe this measure represents a basic clinical concept that does not add clinical value to PQRS because in order to provide effective treatment for asthma, assessment of asthma control is essential. As such, CMS is finalizing its proposal to remove PQRS #064, “Asthma: Assessment of Asthma Control – Ambulatory Care Setting,” which is a process measure, and replace it with the more robust outcome measure, Optimal Asthma - Control Component based on our exception authority under section 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures must be endorsed by NQE.</p>								
0393/083	Effective Clinical Care	<p>Hepatitis C: Confirmation of Hepatitis C Viremia: Percentage of patients aged 18 years and older who are hepatitis C antibody positive seen for an initial evaluation for whom hepatitis C virus (HCV) RNA testing was ordered or previously performed</p> <p>One commenter disagreed with the removal of this measure noting a recent study of four large health systems revealed that “less than two-thirds of persons with positive HCV antibody test had a follow-up RNA test.” Despite these findings, eligible professionals have consistently reported performance rates close to 100% for this measure. With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represents a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. For these reasons, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>	AGA			X				
0103/106	Effective Clinical Care	<p>Adult Major Depressive Disorder (MDD): Comprehensive Depression Evaluation: Diagnosis and Severity: Percentage of patients aged 18 years and</p>	APA	X		X				

NQF/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		<p>older with a new diagnosis or recurrent episode of major depressive disorder (MDD) with evidence that they met the Diagnostic and Statistical Manual of Mental Disorders (DSM)-5 criteria for MDD AND for whom there is an assessment of depression severity during the visit in which a new diagnosis or recurrent episode was identified</p> <p>Commenters disagreed with CMS' proposal to remove this measure noting "appropriate diagnosis and classification of severity are essential in order to ensure appropriate treatment for major depressive disorder. The use of the diagnostic tools included in the measure is currently less than optimal." Furthermore, commenters suggest the other MDD measure (PQRS #370) "does not include screening for bipolar disorder and could potentially exclude some patients from screening." However, CMS continues to believe it represents a clinically diagnostic reference that is commonly utilized as a standard practice of care in order to diagnose and treat mental health disorders. This measure is not robust and does not add clinical value to the PQRS program. It is a goal of CMS to increase the number of outcome-based measures in the PQRS program, and measures that work to appropriately diagnose and classify the severity of illnesses and include quality care action are essential for this effort. For these reasons, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>								
1666/123	Effective Clinical Care	<p>Adult Kidney Disease: Patients On Erythropoiesis-Stimulating Agent (ESA) - Hemoglobin Level > 12.0 g/dL: Percentage of calendar months within a 12-month period during which a hemoglobin level is measured for patients aged 18 years and older with a diagnosis of advanced chronic kidney disease (CKD) (stage 4 or 5, not receiving Renal Replacement Therapy (IRRT)) or End Stage Renal Disease (ESRD) (who are on hemodialysis or peritoneal dialysis) who are also receiving erythropoiesis-stimulating agent (ESA) therapy AND have a hemoglobin level > 12.0 g/dL</p> <p>Some commenters suggested CMS not remove this measure, noting it is "an assessment that is required for making treatment decisions." CMS agrees this</p>	RPA	X		X			X	

NQF/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		measure is both an effective clinical care and overuse measure. However, commenters that agreed with removal of this measure came from specialists who would most likely be reporting this measure. As such, CMS is finalizing its proposal to remove PQRS 123.								
0051/142	Effective Clinical Care	<p>Osteoarthritis (OA): Assessment for Use of Anti-Inflammatory or Analgesic Over-the-Counter (OTC) Medications: Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with an assessment for use of anti-inflammatory or analgesic over-the-counter (OTC) medications</p> <p>A steward has still not been identified for this measure, and for this reason CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>	AMA- PCPI	X		X				
0322/148	Efficiency and Cost Reduction	<p>Back Pain: Initial Visit: The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who had back pain and function assessed during the initial visit to the clinician for the episode of back pain</p> <p>Some commenters supported the removal of this measure while others expressed concern over its removal and the negative impact on anesthesiologists and pain medicine physicians to report PQRS. CMS understands the commenters' concerns. It is a priority for PQRS to ultimately increase the quality of health care, and promoting outcome-based measures is part of this effort. This measure and others in the Back Pain Measure Group represent clinical assessments and recommendations commonly utilized to provide effective treatment for patients diagnosed with back pain, and thus, were determined to be low bar, process-based measures that do not meaningfully contribute to improved patient outcomes or the PQRS program. For this reason, CMS is finalizing its proposal to remove this measure and other measures in the Back Pain Measures Group from the PQRS program in 2015.</p>	NCQA						X	
0319/149	Effective Clinical Care	Back Pain: Physical Exam: Percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received a physical examination at the initial visit to the clinician for the episode of back pain	NCQA						X	

NQE/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		Some commenters supported the removal of this measure while others expressed concern over its removal and the negative impact on anesthesiologists and pain medicine physicians to report PQRS. CMS understands the commenters' concerns. It is a priority for PQRS to ultimately increase the quality of health care and promoting outcome-based measures is part of this effort. This measure and others in the Back Pain Measure Group represent clinical assessments and recommendations commonly utilized to provide effective treatment for patients diagnosed with back pain, and thus, were determined to be low bar, process-based measures that do not meaningfully contribute to improved patient outcomes or the PQRS program. For this reason, CMS is finalizing its proposal to remove this measure and other measures in the Back Pain Measures Group from the PQRS program in 2015.								
0314/150	Effective Clinical Care	<p>Back Pain: Advice for Normal Activities: The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received advice for normal activities at the initial visit to the clinician for the episode of back pain</p> <p>Some commenters expressed concern over the removal of this measure and the negative impact on anesthesiologists and pain medicine physicians to report PQRS. CMS understands the commenters' concerns. It is a priority for PQRS to ultimately increase the quality of health care and promoting outcome-based measures is part of this effort. This measure and others in the Back Pain Measure Group represent clinical assessments and recommendations commonly utilized to provide effective treatment for patients diagnosed with back pain, and thus, were determined to be low bar, process-based measures that do not meaningfully contribute to improved patient outcomes or the PQRS program. For this reason, CMS is finalizing its proposal to remove this measure and other measures in the Back Pain Measures Group from the PQRS program in 2015.</p>	NCQA						X	
0313/151	Effective Clinical Care	Back Pain: Advice Against Bed Rest: The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received advice against bed rest lasting four days or longer at the initial visit to the clinician for	NCQA						X	

NQE/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		<p>the episode of back pain</p> <p>Some commenters supported the removal of this measure while others expressed concern over its removal and the negative impact on anesthesiologists and pain medicine physicians to report PQRS. CMS understands the commenters' concerns. It is a priority for PQRS to ultimately increase the quality of health care and promoting outcome-based measures is part of this effort. This measure and others in the Back Pain Measure Group represent clinical assessments and recommendations commonly utilized to provide effective treatment for patients diagnosed with back pain, and thus, were determined to be low bar, process-based measures that do not meaningfully contribute to improved patient outcomes or the PQRS program. For this reason, CMS is finalizing its proposal to remove this measure and other measures in the Back Pain Measures Group from the PQRS program in 2015.</p>								
0455/157	Patient Safety	<p>Thoracic Surgery: Recording of Clinical Stage Prior to Lung Cancer or Esophageal Cancer Resection: Percentage of surgical patients aged 18 years and older undergoing resection for lung or esophageal cancer who had clinical staging provided prior to surgery</p> <p>Commenters disagreed with removal of this measure noting that removal based on a high-performance rate. With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. For this reason, CMS is finalizing its proposal to remove this measure from 2015 PQRS.</p>	STS	X		X				
0404/159	Effective Clinical Care	<p>HIV/AIDS: CD4+ Cell Count or CD4+ Percentage Performed: Percentage of patients aged 6 months and older with a diagnosis of HIV/AIDS for whom a CD4+ cell count or CD4+ cell percentage was performed at least once every 6 months</p> <p>Commenters disagreed with the removal of this measure based on a rationale of a high performance rate. With a performance rate above 90 percent for multiple consecutive</p>	AMA- PCPI NCQA			X			X	

NQF/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. Furthermore, other commenters agreed with the removal of this measure indicating “this measure is no longer as relevant now that we are measuring CD4 less frequently and such measurement is optional in the Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents for those suppressed for at least 2 years.” For these reasons, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.								
0116/169	Effective Clinical Care	<p>Coronary Artery Bypass Graft (CABG): Antiplatelet Medications at Discharge: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on antiplatelet medication</p> <p>Commenters disagreed with removal of this measure noting that removal based on a high-performance rate. With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. For this reason, CMS is finalizing its proposal to remove this measure from 2015 PQRS.</p>	STS			X			X	
0117/170	Effective Clinical Care	<p>Coronary Artery Bypass Graft (CABG): Beta-Blockers Administered at Discharge: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on beta-blockers</p> <p>Commenters disagreed with removal of this measure noting that removal based on a high-performance rate. With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus</p>	STS			X			X	

NQF/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		on measures with maximal potential for improvement and that answer a clinical performance gap. For this reason, CMS is finalizing its proposal to remove this measure from 2015 PQRS.								
0118/171	Effective Clinical Care	<p>Coronary Artery Bypass Graft (CABG): Anti-Lipid Treatment at Discharge: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on a statin or other lipid-lowering regimen</p> <p>Commenters disagreed with removal of this measure noting that removal based on a high-performance rate. With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. For this reason, CMS is finalizing its proposal to remove this measure from 2015 PQRS.</p>	STS			X			X	
0074/197	Effective Clinical Care	<p>Coronary Artery Disease (CAD): Lipid Control: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who have a LDL-C result < 100 mg/dL OR patients who have a LDL-C result ≥ 100 mg/dL and have a documented plan of care to achieve LDL-C <100 mg/dL, including at a minimum the prescription of a statin</p> <p>Many commenters supported the proposed removal of the measure because the measure may not align with current clinical guidelines. Other commenters disagreed with the removal of this measure indicating the measure is currently in the process of being updated. CMS continues to believe that because of changes to the applicable evidence-based guidelines, this measure is no longer clinically valid. For this reason, CMS is finalizing its proposal to remove this measure from reporting for 2015 PQRS and Medicare Shared Savings Program.</p>	AMA- PCPI ACCF AHA			X		X	X	
0079/198	Effective Clinical Care	<p>Heart Failure: Left Ventricular Ejection Fraction (LVEF) Assessment: Percentage of patients aged 18 years and older with a diagnosis of heart failure for whom the quantitative or qualitative results of a recent or prior [any time in the past] LVEF assessment is documented within a 12</p>	AMA- PCPI ACCF AHA			X			X	

NQE/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		<p>month period</p> <p>Several comments suggested CMS maintain this measure as it is important to clinical practice and has strong impact on patient symptom management. However, CMS continues to believe this measure represents a clinical concept that does not add clinical value to PQRS. LVEF testing is basic assessment for patients with heart failure. For these reasons, CMS is finalizing its proposal to remove this measure from 2015 PQRS.</p>								
N/A /228	Effective Clinical Care	<p>Heart Failure (HF): Left Ventricular Function (LVF) Testing: Percentage of patients 18 years and older with Left Ventricular Function (LVF) testing documented as being performed within the previous 12 months or LVF testing performed prior to discharge for patients who are hospitalized with a principal diagnosis of Heart Failure (HF) during the reporting period</p> <p>Several comments suggested CMS maintain this measure as it is important to clinical practice. However, CMS continues to believe this measure represents a clinical concept that does not add clinical value to PQRS. LVF testing is basic assessment for patients with heart failure. For these reasons, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>	CMS/QIP			X				
N/A/231	Effective Clinical Care	<p>Asthma: Tobacco Use: Screening - Ambulatory Care Setting: Percentage of patients aged 5 through 64 years with a diagnosis of asthma (or their primary caregiver) who were queried about tobacco use and exposure to second hand smoke within their home environment at least once during the one-year measurement period</p> <p>Commenters disagreed with CMS' proposal to replace PQRS #231 (Asthma: Tobacco Use: Screening - Ambulatory Care Setting) with PQRS #226 "Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention" because PQRS #231 includes an age range of 5-64 while the lower bound age for PQRS #226 is 18 years, missing the pediatric population. Furthermore, PQRS #226 does not include the query regarding exposure to second hand smoke which is critical for the 18 and under population with Asthma. However, CMS continues to believe this is measure is</p>	AMA- PCPI NCQA	X		X			X	

NQF/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		appropriate and more broadly applicable and for this reason is finalizing the proposal to remove this measure from 2015 PQRS reporting.								
N/A/232	Effective Clinical Care	<p>Asthma: Tobacco Use: Intervention - Ambulatory Care Setting: Percentage of patients aged 5 through 64 years with a diagnosis of asthma who were identified as tobacco users (or their primary caregiver) who received tobacco cessation intervention at least once during the one-year measurement period</p> <p>Commenters disagreed with CMS' proposal to replace PQRS #232 (Asthma: Tobacco Use: Intervention - Ambulatory Care Setting) with PQRS #226 "Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention" because PQRS #231 and #232 include an age range of 5-64 while the lower bound age for PQRS #226 is 18 years, missing the pediatric population. Furthermore, PQRS #226 does not include the query regarding exposure to second hand smoke which is critical for the 18 and under population with Asthma. However, CMS continues to believe #226 is appropriate and more broadly applicable and for this reason is finalizing its proposal to remove #232 from 2015 PQRS reporting.</p>	AMA- PCPI NCQA	X		X			X	
0457/233	Effective Clinical Care	<p>Thoracic Surgery: Recording of Performance Status Prior to Lung or Esophageal Cancer Resection: Percentage of patients aged 18 years and older undergoing resection for lung or esophageal cancer for whom performance status was documented and reviewed within 2 weeks prior to surgery</p> <p>Commenters disagreed with removal of this measure noting that removal based on a high-performance rate. With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. For this reason, CMS is finalizing its proposal to remove this measure from 2015 PQRS.</p>	STS			X				
0458/234	Patient Safety	Thoracic Surgery: Pulmonary Function Tests Before Major Anatomic Lung Resection (Pneumonectomy, Lobectomy,	STS			X				

NQE/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		<p>or Formal Segmentectomy): Percentage of thoracic surgical patients aged 18 years and older undergoing at least one pulmonary function test within 12 months prior to a major lung resection (pneumonectomy, lobectomy, or formal segmentectomy)</p> <p>Commenters disagreed with removal of this measure noting that removal based on a high-performance rate. With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. For this reason, CMS is finalizing its proposal to remove this measure from 2015 PQRS.</p>								
AQA Adopted /245	Effective Clinical Care	<p>Chronic Wound Care: Use of Wound Surface Culture Technique in Patients with Chronic Skin Ulcers (Overuse Measure)): Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic skin ulcer without the use of a wound surface culture technique</p> <p>Commenters disagreed with removal of this measure based on a rationale of high performance rates. With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. However, other commenters supported the removal of this measure. For these reasons, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>	ASPS	X		X				
AQA Adopted /246	Effective Clinical Care	<p>Chronic Wound Care: Use of Wet to Dry Dressings in Patients with Chronic Skin Ulcers (Overuse Measure)): Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic skin ulcer without a prescription or recommendation to use wet to dry dressings</p> <p>Commenters disagreed with removal of this measure based on a rationale of high performance rates. With a performance rate above 90 percent for multiple consecutive</p>	ASPS	X		X				

NQF/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. However, other commenters supported the removal of this measure. For these reasons, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.								
AQA Adopted/ 247	Effective Clinical Care	<p>Substance Use Disorders: Counseling Regarding Psychosocial and Pharmacologic Treatment Options for Alcohol Dependence: Percentage of patients aged 18 years and older with a diagnosis of current alcohol dependence who were counseled regarding psychosocial AND pharmacologic treatment options for alcohol dependence within the 12-month reporting period</p> <p>Commenters disagreed with removal of this measure based on a rationale of high performance rates. With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>	APA	X		X				AQA
AQA Adopted/ 248	Effective Clinical Care	<p>Substance Use Disorders: Screening for Depression Among Patients with Substance Abuse or Dependence: Percentage of patients aged 18 years and older with a diagnosis of current substance abuse or dependence who were screened for depression within the 12-month reporting period</p> <p>One commenter reported this measure is not applicable to nursing home providers. No other comments were received regarding this measure. CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>	APA	X		X				AQA
N/A /266	Effective Clinical Care	Epilepsy: Seizure Type(s) and Current Seizure Frequency(ies): Percentage of patient visits with a diagnosis of epilepsy who had the type(s) of seizure(s) and	AAN	X		X				

NQF/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		current seizure frequency(ies) for each seizure type documented in the medical record No comments were received regarding this measure. CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.								
N/A/ 267	Effective Clinical Care	Epilepsy: Documentation of Etiology of Epilepsy or Epilepsy Syndrome: All visits for patients with a diagnosis of epilepsy who had their etiology of epilepsy or with epilepsy syndrome(s) reviewed and documented if known, or documented as unknown or cryptogenic No comments were received regarding this measure. CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	AAN	X		X				
N/A/ 269	Effective Clinical Care	Inflammatory Bowel Disease (IBD): Type, Anatomic Location and Activity All Documented: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have documented the disease type, anatomic location and activity, at least once during the reporting period One commenter disagreed with the removal of this measure but did not provide a reason. However, CMS continues to believe that, as a measurement tool, PQRS #269 did not add clinical value to the PQRS Program because in order to provide care for IBD patients, documentation of type, anatomic location and activity would be essential for effective treatment of the disease. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	AGA						X	
N/A/ 272	Effective Clinical Care	Inflammatory Bowel Disease (IBD): Preventive Care: Influenza Immunization: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease for whom influenza immunization was recommended, administered or previously received during the reporting year Commenters were supportive of the removal of this measure and its replacement with PQRS #110 (Preventive Care and Screening: Influenza Immunization) if language were added to the replacement measure to include IBD. CMS continues to believe this measure is duplicative of PQRS	AGA						X	

NQF/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		#110, which is also more broadly applicable. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS and will work with the measure steward to address the question of expanding the age range of PQRS #110.								
N/A/ 273	Effective Clinical Care	<p>Inflammatory Bowel Disease (IBD): Preventive Care: Pneumococcal Immunization: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease that had pneumococcal vaccination administered or previously received</p> <p>Commenters were supportive of the removal of this measure and its replacement with PQRS #111 (Pneumonia Vaccination Status for Older Adults) if language were added to the replacement measure to include IBD patients and address age range differences between the two measures as PQRS #111 does not address the under 65 population. CMS has confirmed with the measure steward for PQRS #111 that the age range can be adjusted. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>	AGA						X	
N/A/295	Effective Clinical Care	<p>Hypertension: Use of Aspirin or Other Antithrombotic Therapy: Percentage of patients aged 30 through 90 years old with a diagnosis of hypertension and are eligible for aspirin or other antithrombotic therapy who were prescribed aspirin or other antithrombotic therapy</p> <p>A steward has not been identified for this measure, and for this reason CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>	ABIM						X	
N/A/ 296	Effective Clinical Care	<p>Hypertension: Complete Lipid Profile: Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who received a complete lipid profile within 60 months</p> <p>A steward has not been identified for this measure, and for this reason CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>	ABIM						X	
N/A/297	Effective Clinical Care	<p>Hypertension: Urine Protein Test: Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who either have chronic kidney disease diagnosis documented or had a urine protein test done within 36 months.</p>	ABIM						X	

NQF/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		Commenters disagreed with the removal of this measure noting that without it, there will “no longer be a quality measure in PQRS that assesses kidney function for people at high risk of chronic kidney disease.” Unfortunately, these measures cannot remain in the PQRS program without a measure steward. Given a steward has not been identified for this measure CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.								
N/A/298	Effective Clinical Care	Hypertension: Annual Serum Creatinine Test: Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who had a serum creatinine test done within 12 months A steward has not been identified for this measure, and for this reason CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	ABIM						X	
N/A/299	Effective Clinical Care	Hypertension: Diabetes Mellitus Screening Test: Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who had a diabetes screening test within 36 months A steward has not been identified for this measure, and for this reason CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	ABIM						X	
N/A/300	Effective Clinical Care	Hypertension: Blood Pressure Control: Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension whose most recent blood pressure was under control (< 140/90 mmHg) A steward has not been identified for this measure, and for this reason CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	ABIM						X	
N/A/ 301	Effective Clinical Care	Hypertension: Low Density Lipoprotein (LDL-C) Control: Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who had most recent LDL cholesterol level under control (at goal) Commenters disagreed with the proposal to remove this measure “until new measures that are more consistent with new and existing guidelines are put in place to replace it.” However, this measure is no longer in accordance with new evidence-based clinical guidelines regarding lipid	ABIM						X	

NQF/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		control. CMS understands the commenters' concerns that removing measures may lead to program gaps; however, it is a priority for PQRS to ultimately increase the quality of health care and this goal was at the forefront of consideration for the removal of these measures. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.								
N/A/302	Effective Clinical Care	Hypertension: Dietary and Physical Activity Modifications Appropriately Prescribed: Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who received dietary and physical activity counseling at least once within 12 months A steward has not been identified for this measure, and for this reason CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	ABIM						X	
2080/341	Efficiency and Cost Reduction	Gap in HIV Medical Visits: Percentage of patients, regardless of age, with a diagnosis of HIV who did not have a medical visit in the last 6 months No comments were received regarding this measure. CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	HRSA			X			X	
Measures Not Finalized as Proposed										
0087/014	Effective Clinical Care	Age-Related Macular Degeneration (AMD): Dilated Macular Examination: Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or hemorrhage AND the level of macular degeneration severity during one or more office visits within 12 months Commenters disagreed with removal of this measure, noting that removal based on a "high-performance rate when EP reporting within the PQRS program is low" may not be appropriate. We have also received strong comments and feedback from outside stakeholders that this measure is still relevant to its eligible professionals. Some commenters note that the "high performance rate" may be skewed and not accurately reflect the existing gap addressed by this measure. CMS agrees with commenters and therefore is not finalizing its proposal to	AAO	X		X				

NQE/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		remove this measure from 2015 PQRS. However, CMS continues to look for better outcome measures, and as such this measure may be considered for removal in a future program year.								
0268/021	Patient Safety	<p>Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin: Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis</p> <p>Commenters disagreed with CMS' proposal to remove this measure, noting "it is premature to remove a measure based on a high-performance rate when the EP reporting rate within the PQRS program is low." CMS agrees with commenters that removing this measure may negatively impact providers' ability to report to PQRS and therefore is not finalizing its proposal to remove this measure from 2015 PQRS. However, CMS is finalizing its proposal to remove the Perioperative Care Measure Group, and for this reason this measure will only be reportable through claims and registry for 2015 PQRS. CMS continues to look for better outcome measures, and as such this measure may be considered for removal in a future program year.</p>	AMA- PCPI NCQA	X		X				
0271/022	Patient Safety	<p>Perioperative Care: Discontinuation of Prophylactic Parenteral Antibiotics (Non-Cardiac Procedures): Percentage of non-cardiac surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics AND who received a prophylactic parenteral antibiotic, who have an order for discontinuation of prophylactic parenteral antibiotics within 24 hours of surgical end time</p> <p>Some commenters disagreed with CMS' proposal to remove this measure, noting "disparate practice patterns among clinicians when selecting the more appropriate prophylactic antibiotic." Furthermore, commenters note it might be premature to remove a measure based on a high-performance rate. CMS agrees with commenters and therefore is not finalizing its proposal to remove this measure from 2015 PQRS. However, CMS is finalizing its</p>	AMA- PCPI NCQA	X		X				

NQE/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		proposal to remove the Perioperative Care Measure Group, and for this reason this measure will only be reportable through claims and registry for 2015 PQRS. CMS continues to look for better outcome measures, and as such this measure may be considered for removal in a future program year.								
0239/023	Patient Safety	<p>Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients): Percentage of surgical patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time</p> <p>Commenters disagreed with removal of this measure noting that removal based on a high-performance rate. CMS agrees with commenters that removing this measure may negatively impact providers' ability to report to PQRS and therefore is not finalizing its proposal to remove this measure from 2015 PQRS. However, CMS is finalizing its proposal to remove the Perioperative Care Measure Group, and for this reason this measure will only be reportable through claims and registry for 2015 PQRS. CMS continues to look for better outcome measures, and as such this measure may be considered for removal in a future program year.</p>	AMA- PCPI NCQA	X		X				
0325/032	Effective Clinical Care	<p>Stroke and Stroke Rehabilitation: Discharged on Antithrombotic Therapy: Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or transient ischemic attack (TIA) who were prescribed antithrombotic therapy at discharge</p> <p>Some commenters agreed while others disagreed with CMS' proposal to remove this measure due to this measure representing a clinical concept that is currently included within inpatient standard of care to decrease risk of complications in patients diagnosed with ischemic or intracranial stroke when clinically indicated. CMS agrees with commenters, and for this reason CMS is not finalizing its proposal to remove this measure from reporting for</p>	AANI	X		X				

NQF/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		2015 PQRS. However, CMS continues to look for better outcome measures, and as such this measure may be considered for removal in a future program year.								
0241/033	Effective Clinical Care	<p>Stroke and Stroke Rehabilitation: Anticoagulant Therapy Prescribed for Atrial Fibrillation (AF) at Discharge: Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or transient ischemic attack (TIA) with documented permanent, persistent, or paroxysmal atrial fibrillation who were prescribed an anticoagulant at discharge</p> <p>Commenters disagreed with CMS' proposal to remove this measures based on the rationale that they represent clinical concepts that are currently included within inpatient standards of care to improve patient outcomes for those diagnosed with ischemic or intracranial stroke when clinically indicated. Commenters maintain that these clinical concepts are appropriate for measurement at the individual physician level in addition to the facility level to help ensure the continuous care of stroke patients. CMS agrees with commenters, and for this reason CMS is not finalizing its proposal to remove this measure from reporting for 2015 PQRS. However, CMS continues to look for better outcome measures, and as such this measure may be considered for removal in a future program year.</p>	AANI			X				
0091/051	Effective Clinical Care	<p>Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation: Percentage of patients aged 18 years and older with a diagnosis of COPD who had spirometry evaluation results documented</p> <p>A steward has been identified for this measure, and for this reason CMS is not finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>	American Thoracic Society			X			X	
0102/052	Effective Clinical Care	<p>Chronic Obstructive Pulmonary Disease (COPD): Inhaled Bronchodilator Therapy: Percentage of patients aged 18 years and older with a diagnosis of COPD and who have an FEV₁/FVC less than 60% and have symptoms who were prescribed an inhaled bronchodilator</p> <p>A steward has been identified for this measure, and for this reason CMS is not finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>	American Thoracic Society			X			X	

NQF/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
0050/109	Person and Caregiver- Centered Experience and Outcomes	<p>Osteoarthritis (OA): Function and Pain Assessment: Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain</p> <p>A steward has been identified for this measure, and for this reason CMS is not finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>	AAOS			X				
0566/140	Effective Clinical Care	<p>Age-Related Macular Degeneration (AMD): Counseling on Antioxidant Supplement: Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) or their caregiver(s) who were counseled within 12 months on the benefits and/or risks of the Age-Related Eye Disease Study (AREDS) formulation for preventing progression of AMD</p> <p>Commenters disagreed with removal of this measure noting that removal based on a “high-performance rate when EP reporting within the PQRS program is low” may not be appropriate. CMS agrees with commenters, and for this reason CMS is not finalizing its proposal to remove this measure from reporting for 2015 PQRS. However, CMS continues to look for better outcome measures, and as such this measure may be considered for removal in a future program year.</p>	AAO	X		X				
0508/146	Efficiency and Cost Reduction	<p>Radiology: Inappropriate Use of “Probably Benign” Assessment Category in Mammography Screening: Percentage of final reports for screening mammograms that are classified as “probably benign”</p> <p>Commenters disagreed with the removal of this measure based on a rationale of a high performance rate. Furthermore one commenter notes “this measure is important in that it ensures the integrity of the complete mammography audit.” CMS agrees with commenters, and for this reason CMS is not finalizing its proposal to remove this measure from reporting for 2015 PQRS. However, CMS continues to look for better outcome measures, and as such this measure may be considered for removal in a future program year.</p>	AC Radiology / AMA- PCPI	X		X				
N/A/147	Communic ation and Care Coordination	<p>Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy: Percentage of final reports for all patients,</p>	SNMMI	X		X				

NQF/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
	n	<p>regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (for example, x-ray, MRI, CT, etc.) that were performed.</p> <p>A steward has been identified for this measure, and as a result CMS is not finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>								
0115/168	Effective Clinical Care	<p>Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason</p> <p>Commenters disagreed with removal of this measure noting that removal based on a high-performance rate. CMS agrees with commenters that this may negatively impact the ability of certain specialties to report PQRS, and for this reason CMS is not finalizing its proposal to remove this measure from reporting for 2015 PQRS. However, CMS continues to look for better outcome measures, and as such this measure may be considered for removal in a future program year.</p>	STS			X			X	
AQA Adopted/ 173	Community /Population Health	<p>Preventive Care and Screening: Unhealthy Alcohol Use – Screening: Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method within 24 months</p> <p>A measure steward has been identified for this measure, and as such CMS is not finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>	AMA- PCPI			X			X	
0643/243	Effective Clinical Care	<p>Cardiac Rehabilitation Patient Referral from an Outpatient Setting: Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis</p>	ACCF AHA			X				

NQE/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		<p>who were referred to a CR program</p> <p>Commenters disagreed with CMS' proposal to remove this measure, suggesting that “while the clinical condition may initiate in the inpatient setting, the clinical process being measured is limited to the outpatient setting and would therefore add clinical value to outpatient care of the cardiac rehabilitation patient.” Further, commenters note that there is “clear evidence that processes to improve referral of eligible patients to cardiac rehabilitation result in improved cardiac rehabilitation participation rates and improved patient outcomes.” CMS agrees with the commenters, and for this reason CMS is not finalizing its proposal to remove this measure from reporting for 2015 PQRS. However, CMS continues to look for better outcome measures, and as such this measure may be considered for removal in a future program year.</p>								
N/A/ 257	Effective Clinical Care	<p>Statin Therapy at Discharge after Lower Extremity Bypass (LEB): Percentage of patients aged 18 years and older undergoing infra-inguinal lower extremity bypass who are prescribed a statin medication at discharge</p> <p>Commenters disagreed with the proposed removal of this measure on the basis that the measure represents a current standard of care. CMS agrees with commenters, and for this reason CMS is not finalizing its proposal to remove this measure from reporting for 2015 PQRS. However, CMS continues to look for better outcome measures, and as such this measure may be considered for removal in a future program year.</p>	SVS			X				
N/A/ 261	Communic ation and Care Coordination	<p>Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness: Percentage of patients aged birth and older referred to a physician (preferably a physician specially trained in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness</p> <p>Commenters disagreed with CMS' proposal to remove this measure with the rationale that it represents a clinical concept that is common practice in order to provide effective treatment for patients. Commenters request reconsideration for CY 2015 to ensure audiologists have enough clinically-relevant measures to report. For</p>	AQC	X		X				

NQF/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		this reason, CMS is not finalizing its proposal to remove this measure from reporting in 2015 PQRS.								
N/A/276	Effective Clinical Care	<p>Sleep Apnea: Assessment of Sleep Symptoms: Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea that includes documentation of an assessment of sleep symptoms, including presence or absence of snoring and daytime sleepiness</p> <p>A steward has been identified for this measure and for this reason CMS is not finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>	AASM/ AMA- PCPI						X	
N/A/277	Effective Clinical Care	<p>Sleep Apnea: Severity Assessment at Initial Diagnosis: Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis</p> <p>A steward has been identified for this measure, and for this reason CMS is not finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>	AASM/ AMA- PCPI						X	
N/A/278	Effective Clinical Care	<p>Sleep Apnea: Positive Airway Pressure Therapy Prescribed: Percentage of patients aged 18 years and older with a diagnosis of moderate or severe obstructive sleep apnea who were prescribed positive airway pressure therapy</p> <p>A steward has been identified for this measure, and for this reason CMS is not finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>	AASM/ AMA- PCPI						X	
N/A/279	Effective Clinical Care	<p>Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy: Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured</p> <p>A steward has been identified for this measure, and for this reason CMS is not finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>	AASM/ AMA- PCPI						X	
N/A/335	Patient Safety	<p>Maternity Care: Elective Delivery or Early Induction Without Medical Indication at ≥ 37 and < 39 Weeks: Percentage of patients, regardless of age,</p>	AMA- PCPI			X				

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		<p>who gave birth during a 12-month period who delivered a live singleton at ≥ 37 and < 39 weeks of gestation completed who had elective deliveries or early inductions without medical indication</p> <p>A steward has been identified for this measure, and for this reason CMS is not finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>								
N/A/336	Communication and Care Coordination	<p>Maternity Care: Post-Partum Follow-Up and Care Coordination: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for post-partum care within 8 weeks of giving birth who received a breast feeding evaluation and education, post-partum depression screening, post-partum glucose screening for gestational diabetes patients, and family and contraceptive planning</p> <p>A steward has been identified for this measure, and for this reason CMS is not finalizing its proposal to remove this measure from reporting in 2015 PQRS.</p>	AMA-PCPI			X				

¥ Measure details including titles, descriptions and measure owner information may vary during a particular program year. This is due to the timing of measure specification preparation and the measure versions used by the various reporting options/methods. Please refer to the measure specifications that apply for each of the reporting options/methods for specific measure details.

In Table 56, we provide our responses and final decisions related to our proposals to change the way in which previously established measures in the PQRS will be reported beginning in 2015 (79 FR 40441).

TABLE 56: Existing Individual Quality Measures and Those Included in Measures Groups for the PQRS for Which Measure Reporting Updates Will Be Effective Beginning in 2015

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
Measures Finalized as Proposed											
006 4/0 02	163 v3	Effective Clinical Care	<p>Diabetes: Low Density Lipoprotein (LDL-C) Control (<100 mg/dl): Percentage of patients 18–75 years of age with diabetes whose LDL-C was adequately controlled (< 100 mg/dL) during the measurement period</p> <p>Commenters expressed concern with maintaining this measure in PQRS for EHR reporting only for the “sake of alignment with the EHR Incentive Program especially in the face of changing [clinical] evidence.” However, due to our desire to align with the EHR Incentive Program, CMS will not make changes to EHR measures until the EHR Incentive Program is able to change this measure. CMS understands commenters’ concerns and will track these issues for future program years when changes are possible. CMS is finalizing its proposal to make this measure reportable in 2015 PQRS through EHR only.</p>	NCQA				X			MU2 Million Hearts
006 7/0 06		Effective Clinical Care	<p>Coronary Artery Disease (CAD): Antiplatelet Therapy: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12 month period who were prescribed aspirin or clopidogrel</p> <p>Several commenters were concerned with CMS’ proposal to eliminate the claims-based reporting option for various measures, noting that not all eligible professionals have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters’ concerns and believes that removal of the claims-based reporting option will not negatively impact a significant number of providers reporting these measures. CMS also received comments supporting inclusion of the measure in the Shared Savings Program CAD Composite measure but with composite measure testing and NQF review. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS as part of its goal to lower the data error rate and decrease provider burden. CMS will not finalize adding this measure in the Shared Savings Program CAD Composite.</p>	AMA- PCPI ACCF AHA			X		X	X	ACO
010 5/0	128 v3	Effective Clinical	Anti-Depressant Medication Management: Percentage of patients 18 years of age and	NCQA				X			MU2

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description*	Measure Steward	Claims	CSV	Registry	EHR	GPPO (Web Interface)	Measures Groups	Other Quality Reporting Programs
09		Care	<p>older who were diagnosed with major depression and treated with antidepressant medication, and who remained on antidepressant medication treatment. Two rates are reported:</p> <p>a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks).</p> <p>b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).</p> <p>CMS is finalizing its proposal to change the reporting option of PQRS #9 to EHR-only reporting as part of its efforts to align with the EHR Incentive Program. PQRS would otherwise propose to remove this measure from PQRS, as it is a process measure that is analytically challenging to report.</p>								
008 8/0 18	167 v3	Effective Clinical Care	<p>Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy: Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed which included documentation of the level of severity of retinopathy and the presence or absence of macular edema during one or more office visits within 12 months</p> <p>One commenter disagreed with the removal of this measure. CMS initially wanted to propose removal of this measure as eligible professionals are consistently meeting performance on this measure with performance rates close to 100%. However, due to our desire to align with the EHR Incentive Program, under which this measure is also available for reporting in 2015, CMS proposed to maintain this measure in PQRS for EHR reporting only, removing all other reporting options, until the EHR Incentive Program can change this measure. CMS is finalizing removal of this measure from reporting for 2015 PQRS for all other reporting options.</p>	AMA- PCPI NCQA				X			MU2
013 4/0 43		Effective Clinical Care	<p>Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG Surgery: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who received an IMA graft</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that not all eligible professionals have the</p>	STS			X			X	

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description*	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns and believes that removal of the claims-based reporting option will not negatively impact a significant number of providers reporting these measures. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS as part of its goal to lower the data error rate and decrease provider burden.								
037 7/0 67		Effective Clinical Care	<p>Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow: Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) or an acute leukemia who had baseline cytogenetic testing performed on bone marrow</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that not all eligible professionals have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns and believes that removal of the claims-based reporting option will not negatively impact a significant number of providers reporting these measures. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS as part of its goal to lower the data error rate and decrease provider burden.</p>	AMA- PCPI ASH			X				
037 8/0 68		Effective Clinical Care	<p>Hematology: Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy: Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) who are receiving erythropoietin therapy with documentation of iron stores within 60 days prior to initiating erythropoietin therapy</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that not all eligible professionals have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns and believes that removal of the claims-based reporting option will not negatively impact a significant</p>	AMA- PCPI ASH			X				

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description*	Measure Steward	Claims	CSV	Registry	EHR	GPPO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			number of providers reporting these measures. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015.								
038 0/0 69		Effective Clinical Care	<p>Hematology: Multiple Myeloma: Treatment with Bisphosphonates: Percentage of patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission, who were prescribed or received intravenous bisphosphonate therapy within the 12-month reporting period</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that not all eligible professionals have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns and believes that removal of the claims-based reporting option will not negatively impact a significant number of providers reporting these measures. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015.</p>	AMA- PCPI ASH			X				
037 9/0 70		Effective Clinical Care	<p>Hematology: Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry: Percentage of patients aged 18 years and older seen within a 12 month reporting period with a diagnosis of chronic lymphocytic leukemia (CLL) made at any time during or prior to the reporting period who had baseline flow cytometry studies performed and documented in the chart</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that not all eligible professionals have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns and believes that removal of the claims-based reporting option will not negatively impact a significant number of providers reporting these measures. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015.</p>	AMA- PCPI ASH			X				
039 5 /08 4		Effective Clinical Care	<p>Hepatitis C: Ribonucleic Acid (RNA) Testing Before Initiating Treatment: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who started antiviral treatment within the 12 month reporting period for whom quantitative hepatitis C virus (HCV) RNA</p>	AGA						X	

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description*	Measure Steward	Claims	CSV	Registry	EHR	GPPO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			<p>testing was performed within 12 months prior to initiation of antiviral treatment</p> <p>While several comments were concerned with the removal of reporting options for some measures, CMS is finalizing its proposal to make this individual measure reportable via measures groups-only to lessen the burden of eligible professionals reporting individual measures based on the current requirement of nine measures over three domains. While removing reporting options could be seen as increasing burden for eligible professionals, as they have fewer choices to report this measure, we do not believe this is the case with reporting via measures groups. For example, an individual eligible professional reporting via a measures group only need to report on a minimum of 6 measures rather than a minimum of 9 measures covering 3 NQS domains, as is the case with reporting individual measures.</p>								
039 6 /08 5		Effective Clinical Care	<p>Hepatitis C: HCV Genotype Testing Prior to Treatment: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who started antiviral treatment within the 12 month reporting period for whom hepatitis C virus (HCV) genotype testing was performed within 12 months prior to initiation of antiviral treatment</p> <p>While several comments were concerned with the removal of reporting options for some measures, CMS is finalizing its proposal to make this individual measure reportable via measures groups-only to lessen the burden of eligible professionals reporting individual measures based on the current requirement of nine measures over three domains. While removing reporting options could be seen as increasing burden for eligible professionals, as they have fewer choices to report this measure, we do not believe this is the case with reporting via measures groups. For example, an individual eligible professional reporting via a measures group only need to report on a minimum of 6 measures rather than a minimum of 9 measures covering 3 NQS domains, as is the case with reporting individual measures</p>	AGA						X	
039 8/0 87		Effective Clinical Care	<p>Hepatitis C: Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Testing Between 4-12 Weeks After Initiation of Treatment: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for</p>	AGA						X	

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description*	Measure Steward	Claims	CSV	Registry	EHR	GPPO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			<p>whom quantitative hepatitis C virus (HCV) RNA testing was performed between 4-12 weeks after the initiation of antiviral treatment</p> <p>While several comments were concerned with the removal of reporting options for some measures, CMS is finalizing its proposal to make this individual measure reportable via measures groups-only to lessen the burden of eligible professionals reporting individual measures based on the current requirement of nine measures over three domains. While removing reporting options could be seen as increasing burden for eligible professionals, as they have fewer choices to report this measure, we do not believe this is the case with reporting via measures groups. For example, an individual eligible professional reporting via a measures group only need to report on a minimum of 6 measures rather than a minimum of 9 measures covering 3 NQS domains, as is the case with reporting individual measures</p>								
038 9 /10 2	129 v3	Efficiency and Cost Reduction	<p>Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that not all eligible professionals have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns and believes that removal of the claims-based reporting option will not negatively impact a significant number of providers reporting these measures. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015.</p>	AMA- PCPI			X	X			MU2
039 0 /10 4		Effective Clinical Care	<p>Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Prostate Cancer Patients: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed adjuvant hormonal therapy (GnRH [gonadotropin-releasing</p>	AMA- PCPI			X				

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description*	Measure Steward	Claims	CSV	Registry	EHR	GPPO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			hormone] agonist or antagonist) Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that not all eligible professionals have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns and believes that removal of the claims-based reporting option will not negatively impact a significant number of providers reporting these measures. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015.								
010 4/1 07	161 v3	Effective Clinical Care	Adult Major Depressive Disorder (MDD): Suicide Risk Assessment: Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified CMS is finalizing its proposal to change the reporting option of PQRS #107 to EHR-only reporting as part of its efforts to align with the EHR Incentive Program when PQRS would otherwise propose to remove this measure from PQRS, as it is a process measure that is analytically challenging to report. PQRS will keep this measure as EHR-reportable until the EHR Incentive Program is able to change this measure.	AMA- PCPI				X			MU2
005 4 /10 8		Effective Clinical Care	Rheumatoid Arthritis (RA): Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy: Percentage of patients aged 18 years and older who were diagnosed with RA and were prescribed, dispensed, or administered at least one ambulatory prescription for a disease-modifying anti-rheumatic drug (DMARD) While several comments were concerned with the removal of reporting options for some measures, CMS is finalizing its proposal to make this individual measure reportable via measures groups-only to lessen the burden of eligible professionals reporting individual measures based on the current requirement of nine measures over three domains. While removing reporting options could be seen as increasing burden for eligible professionals, as they have fewer choices to report this measure, we do not believe this is the case with reporting via measures groups. For example, an individual	NCQA						X	

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description [*]	Measure Steward	Claims	CSV	Registry	EHR	GPPO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			eligible professional reporting via a measures group only need to report on a minimum of 6 measures rather than a minimum of 9 measures covering 3 NQS domains, as is the case with reporting individual measures								
166 8 /12 1		Effective Clinical Care	<p>Adult Kidney Disease: Laboratory Testing (Lipid Profile): Percentage of patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) who had a fasting lipid profile performed at least once within a 12-month period</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that not all eligible professionals have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns and believes that removal of the claims-based reporting option will not negatively impact a significant number of providers reporting these measures. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015.</p>	RPA			X			X	
AQ A Ad opt ed /12 2		Effective Clinical Care	<p>Adult Kidney Disease: Blood Pressure Management: Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) with a blood pressure < 140/90 mmHg OR ≥ 140/90 mmHg with a documented plan of care</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that not all eligible professionals have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns and believes that removal of the claims-based reporting option will not negatively impact a significant number of providers reporting these measures. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015.</p>	RPA			X			X	AQA
040 5 /16 0	52v 3	Effective Clinical Care	<p>HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis: Percentage of patients aged 6 weeks and older with a diagnosis of HIV/AIDS who were prescribed Pneumocystis Jiroveci Pneumonia (PCP) prophylaxis</p>	NCQA						X	MU2

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description [¶]	Measure Steward	Claims	CSV	Registry	EHR	GP/RO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			While several comments were concerned with the removal of reporting options for some measures, CMS is finalizing its proposal to make this individual measure reportable via measures groups-only to lessen the burden of eligible professionals reporting individual measures based on the current requirement of nine measures over three domains. While removing reporting options could be seen as increasing burden for eligible professionals, as they have fewer choices to report this measure, we do not believe this is the case with reporting via measures groups. For example, an individual eligible professional reporting via a measures group only need to report on a minimum of 6 measures rather than a minimum of 9 measures covering 3 NQS domains, as is the case with reporting individual measures								
AQ A Ad opt ed/ 176		Effective Clinical Care	Rheumatoid Arthritis (RA): Tuberculosis Screening: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 6 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD) While several comments were concerned with the removal of reporting options for some measures, CMS is finalizing its proposal to make this individual measure reportable via measures groups-only to lessen the burden of eligible professionals reporting individual measures based on the current requirement of nine measures over three domains. While removing reporting options could be seen as increasing burden for eligible professionals, as they have fewer choices to report this measure, we do not believe this is the case with reporting via measures groups. For example, an individual eligible professional reporting via a measures group only need to report on a minimum of 6 measures rather than a minimum of 9 measures covering 3 NQS domains, as is the case with reporting individual measures	AC Rheumat ology						X	AQA
AQ A Ad opt ed/ 177		Effective Clinical Care	Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease activity within 12 months While several comments were concerned	AC Rheumat ology						X	AQA

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			with the removal of reporting options for some measures, CMS is finalizing its proposal to make this individual measure reportable via measures groups-only to lessen the burden of eligible professionals reporting individual measures based on the current requirement of nine measures over three domains. While removing reporting options could be seen as increasing burden for eligible professionals, as they have fewer choices to report this measure, we do not believe this is the case with reporting via measures groups. For example, an individual eligible professional reporting via a measures group only need to report on a minimum of 6 measures rather than a minimum of 9 measures covering 3 NQS domains, as is the case with reporting individual measures								
AQ A Ad opt ed/ 179		Effective Clinical Care	Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease prognosis at least once within 12 months While several comments were concerned with the removal of reporting options for some measures, CMS is finalizing its proposal to make this individual measure reportable via measures groups-only to lessen the burden of eligible professionals reporting individual measures based on the current requirement of nine measures over three domains. While removing reporting options could be seen as increasing burden for eligible professionals, as they have fewer choices to report this measure, we do not believe this is the case with reporting via measures groups. For example, an individual eligible professional reporting via a measures group only need to report on a minimum of 6 measures rather than a minimum of 9 measures covering 3 NQS domains, as is the case with reporting individual measures	AC Rheumat ology						X	AQA
AQ A Ad opt ed/ 18 0		Effective Clinical Care	Rheumatoid Arthritis (RA): Glucocorticoid Management: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months While several comments were concerned	AC Rheumat ology						X	AQA

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description*	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			with the removal of reporting options for some measures, CMS is finalizing its proposal to make this individual measure reportable via measures groups-only to lessen the burden of eligible professionals reporting individual measures based on the current requirement of nine measures over three domains. While removing reporting options could be seen as increasing burden for eligible professionals, as they have fewer choices to report this measure, we do not believe this is the case with reporting via measures groups. For example, an individual eligible professional reporting via a measures group only need to report on a minimum of 6 measures rather than a minimum of 9 measures covering 3 NQS domains, as is the case with reporting individual measures								
039 9 /18 3		Community / Population Health	<p>Hepatitis C: Hepatitis A Vaccination in Patients with Hepatitis C Virus (HCV): Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who have received at least one injection of hepatitis A vaccine, or who have documented immunity to hepatitis A</p> <p>While several comments were concerned with the removal of reporting options for some measures, CMS is finalizing its proposal to make this individual measure reportable via measures groups-only to lessen the burden of eligible professionals reporting individual measures based on the current requirement of nine measures over three domains. While removing reporting options could be seen as increasing burden for eligible professionals, as they have fewer choices to report this measure, we do not believe this is the case with reporting via measures groups. For example, an individual eligible professional reporting via a measures group only need to report on a minimum of 6 measures rather than a minimum of 9 measures covering 3 NQS domains, as is the case with reporting individual measures</p>	AGA						X	
038 6 /19 4		Effective Clinical Care	<p>Oncology: Cancer Stage Documented: Percentage of patients, regardless of age, with a diagnosis of cancer who are seen in the ambulatory setting who have a baseline American Joint Committee on Cancer (AJCC) cancer stage or documentation that the cancer is metastatic in the medical record at least once during the 12 month reporting period</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based</p>	AMA- PCPI ASCO			X				

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description*	Measure Steward	Claims	CSV	Registry	EHR	GPPO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			reporting option for various measures, noting that not all eligible professionals have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns and believes that removal of the claims-based reporting option will not negatively impact a significant number of providers reporting these measures. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS as part of its goal to lower the data error rate and decrease provider burden. Note that this measure is no longer part of a measures group as well.								
002 2/2 38	156 v3	Patient Safety	<p>Use of High-Risk Medications in the Elderly: Percentage of patients 66 years of age and older who were ordered high-risk medications. Two rates are reported</p> <p>a. Percentage of patients who were ordered at least one high-risk medication.</p> <p>b. Percentage of patients who were ordered at least two different high-risk medications</p> <p>No comments were received regarding this measure. CMS is finalizing its proposal to add registry as a reporting option for this measure in 2015 PQRS.</p>	NCQA			X	X			MU2
007 5/2 41	182 v4	Effective Clinical Care	<p>Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL-C Control (<100 mg/dL): Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had each of the following during the measurement period: a complete lipid profile and LDL-C was adequately controlled (< 100 mg/dL)</p> <p>CMS is finalizing its proposal to change the reporting option of PQRS #241 to EHR-only reporting as part of its efforts to align with the EHR Incentive Program when PQRS would otherwise propose to remove this measure from PQRS 2015. PQRS will keep this measure as EHR reportable until the EHR Incentive Program can change this measure.</p>	NCQA				X			MU2 Million Hearts
N/ A /32		Effective Clinical Care	<p>Pediatric Kidney Disease: Adequacy of Volume Management: Percentage of calendar months within a 12-month period</p>	RPA			X				

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description*	Measure Steward	Claims	CSV	Registry	EHR	GPPO (Web Interface)	Measures Groups	Other Quality Reporting Programs
7			<p>during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) undergoing maintenance hemodialysis in an outpatient dialysis facility have an assessment of the adequacy of volume management from a nephrologist</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that not all eligible professionals have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns and believes that removal of the claims-based reporting option will not negatively impact a significant number of providers reporting these measures. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS as part of its goal to lower the data error rate and decrease provider burden.</p>								
166 7 /32 8		Effective Clinical Care	<p>Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL: Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis or peritoneal dialysis have a hemoglobin level < 10 g/dL</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that not all eligible professionals have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns and believes that removal of the claims-based reporting option will not negatively impact a significant number of providers reporting these measures. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015.</p>	RPA			X				
208 2 /33 8		Effective Clinical Care	<p>HIV Viral Load Suppression: The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last viral load test during the measurement year</p> <p>While several comments were concerned with the removal of reporting options for some measures, CMS is finalizing its proposal to make this individual measure reportable via measures groups-only to lessen</p>	HRSA						X	

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description [*]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			the burden of eligible professionals reporting individual measures based on the current requirement of nine measures over three domains. While removing reporting options could be seen as increasing burden for eligible professionals, as they have fewer choices to report this measure, we do not believe this is the case with reporting via measures groups. For example, an individual eligible professional reporting via a measures group only need to report on a minimum of 6 measures rather than a minimum of 9 measures covering 3 NQS domains, as is the case with reporting individual measures								
208 3 /33 9		Effective Clinical Care	<p>Prescription of HIV Antiretroviral Therapy: Percentage of patients, regardless of age, with a diagnosis of HIV prescribed antiretroviral therapy for the treatment of HIV infection during the measurement year</p> <p>While several comments were concerned with the removal of reporting options for some measures, CMS is finalizing its proposal to make this individual measure reportable via measures groups-only to lessen the burden of eligible professionals reporting individual measures based on the current requirement of nine measures over three domains. While removing reporting options could be seen as increasing burden for eligible professionals, as they have fewer choices to report this measure, we do not believe this is the case with reporting via measures groups. For example, an individual eligible professional reporting via a measures group only need to report on a minimum of 6 measures rather than a minimum of 9 measures covering 3 NQS domains, as is the case with reporting individual measures</p>	HRSA						X	
207 9 /34 0		Efficiency and Cost Reduction	<p>HIV Medical Visit Frequency: Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits</p> <p>This measure was included on this table in error in the proposed rule. There are no changes proposed for this measure in 2015 PQRS. This measure was reportable through measure groups only in PQRS 2014 and will continue to be similarly reportable in PQRS 2015.</p>	HRSA						X	
071 0/ 370	159 v3	Effective Clinical Care	Depression Remission at Twelve Months: Adult patients age 18 and older with major depression or dysthymia and an initial PHQ-9 score > 9 who demonstrate remission at	MNCM				X	X		MU2

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description [*]	Measure Steward	Claims	CSV	Registry	EHR	GP/RO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			<p>twelve months defined as PHQ-9 score less than 5. This measure applies to both patients with newly diagnosed and existing depression whose current PHQ-9 score indicates a need for treatment</p> <p>CMS did not receive any comments regarding the proposal to add registry as a reporting option for this measure. As such, CMS is finalizing this proposal for 2015 PQRS.</p>								
Measures Not Finalized as Proposed											
008 6/0 12	143 v3	Effective Clinical Care	<p>Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation: Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more office visits within 12 months</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.</p>	AMA- PCPI NCQA	X		X	X			MU2
008 9/0 19	142 v3	Effective Clinical Care	<p>Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care: Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to</p>	AMA- PCPI NCQA	X		X	X			MU2

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description*	Measure Steward	Claims	CSV	Registry	EHR	GPPO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.								
004 5/0 24		Communication and Care Coordination	<p>Osteoporosis: Communication with the Physician Managing On-going Care Post-Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older: Percentage of patients aged 50 years and older treated for a hip, spine or distal radial fracture with documentation of communication with the physician managing the patient's on-going care that a fracture occurred and that the patient was or should be tested or treated for osteoporosis</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Furthermore, this measure is a preventive care measure. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.</p>	AMA-PCPI NCQA	X		X				
004 6/0 39		Effective Clinical Care	<p>Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older who have a central dual-energy X-ray absorptiometry (DXA) measurement ordered or performed at least once since age 60 or pharmacologic therapy prescribed within 12 months</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the</p>	AMA-PCPI NCQA	X		X			X	

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description*	Measure Steward	Claims	CSV	Registry	EHR	GPPO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS identified this measure as a broadly applicable, preventive care measure. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.								
004 8/0 40		Effective Clinical Care	<p>Osteoporosis: Management Following Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older: Percentage of patients <u>aged 50 years and older</u> with fracture of the hip, spine, or distal radius who had a central dual-energy X-ray absorptiometry (DXA) measurement ordered or performed or pharmacologic therapy prescribed</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.</p>	AMA- PCPI NCQA	X		X				
009 7/0 46		Communica tion and Care Coordination	<p>Medication Reconciliation: Percentage of patients aged 18 years and older discharged from any inpatient facility (for example, hospital, skilled nursing facility, or rehabilitation facility) and seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care who had a reconciliation of the discharge medications with the current medication list in the outpatient medical record documented. This measure is reported as two rates stratified by age group:</p> <p>Reporting Age Criteria 1: 18-64 years of age Reporting Age Criteria 2: 65 years and older</p>	AMA- PCPI NCQA	X		X				

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description*	Measure Steward	Claims	CSV	Registry	EHR	GP/RO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.								
010 0/0 50		Person and Caregiver- Centered Experience and Outcomes	<p>Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Furthermore, CMS identified this measure as a preventive care measure. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.</p>	NCQA AMA- PCPI	X		X				
009 0/0 54		Effective Clinical Care	<p>Emergency Medicine: 12-Lead Electrocardiogram (ECG) Performed for Non-Traumatic Chest Pain: Percentage of patients aged 40 years and older with an emergency department discharge diagnosis of non-traumatic chest pain who had a 12-lead electrocardiogram (ECG) performed</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting</p>	AMA- PCPI NCQA	X		X				

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description*	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.								
038 7/0 71	140 v3	Effective Clinical Care	<p>Breast Cancer: Hormonal Therapy for Stage IC - IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer: Percentage of female patients aged 18 years and older with Stage IC through IIIC, ER or PR positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.</p>	AMA- PCPI ASCO NCCN	X		X	X		X	MU2
038 5/0 72	141 v3	Effective Clinical Care	<p>Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients: Percentage of patients aged 18 through 80 years with AJCC Stage III colon cancer who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy within the 12-month reporting period</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the</p>	AMA- PCPI ASCO NCCN	X		X	X		X	MU2

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description*	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.								
N/ A/1 12		Effective Clinical Care	<p>Breast Cancer Screening: Percentage of women 50 through 74 years of age who had a mammogram to screen for breast cancer within 27 months</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS identified this as a broadly applicable, preventive care measure. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.</p>	NCQA	X		X	X	X	X	MU2
003 4 /11 3	130 v3	Effective Clinical Care	<p>Colorectal Cancer Screening: Percentage of patients 50 through 75 years of age who had appropriate screening for colorectal cancer</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS identified this as a broadly applicable, preventive care measure. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.</p>	NCQA	X		X	X	X	X	MU2

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description [*]	Measure Steward	Claims	CSV	Registry	EHR	GPPO (Web Interface)	Measures Groups	Other Quality Reporting Programs
005 5 /11 7	131 v3	Effective Clinical Care	<p>Diabetes: Eye Exam: Percentage of patients 18 through 75 years of age with a diagnosis of diabetes (type 1 and type 2) who had a retinal or dilated eye exam by an eye care professional in the measurement period or a negative retinal or dilated eye exam (negative for retinopathy) in the year prior to the measurement period</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. In addition, many commenters supported the inclusion of the measure within the Shared Savings Program Diabetes Composite, but requested testing of the Composite measure and submission to NQF. Some commenters did not support the addition of a process measure to the Shared Savings Program measure set and questioned the measure's link to improving outcomes. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years. CMS will finalize adding the measure to the Shared Savings Program Diabetes Composite due to its clinical importance, alignment with PQRS, and stakeholder support.</p>	NCQA	X		X	X	X	X	ACO MU2
006 2 /11 9	134 v3	Effective Clinical Care	<p>Diabetes: Medical Attention for Nephropathy: The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the</p>	NCQA	X		X	X		X	MU2

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description*	Measure Steward	Claims	CSV	Registry	EHR	GP/RO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			claims-based option. Furthermore, CMS identified this measure as a preventive care measure. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.								
056 3 /14 1		Communication and Care Coordination	<p>Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care: Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre-intervention level, a plan of care was documented within 12 months</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.</p>	AAO	X		X				
005 6 /16 3	123 v3	Effective Clinical Care	<p>Diabetes: Foot Exam: Percentage of patients aged 18-75 years of age with diabetes who had a foot exam during the measurement period</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Furthermore, CMS</p>	NCQA	X		X	X		X	ACO MU2

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description*	Measure Steward	Claims	CSV	Registry	EHR	GPPO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			identified this as a preventive care measure. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.								
065 9 /18 5		Communication and Care Coordination	<p>Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use: Percentage of patients aged 18 years and older receiving a surveillance colonoscopy with a history of a prior adenomatous polyp(s) in previous colonoscopy findings, who had an interval of 3 or more years since their last colonoscopy</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.</p>	AGA ASGE ACG	X		X				
006 8/2 04	164 v3	Effective Clinical Care	<p>Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic: Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period and who had documentation of use of aspirin or another antithrombotic during the measurement period</p> <p>Commenters expressed concern with maintaining this measure in PQRS for EHR reporting only for the "sake of alignment with the EHR Incentive Program especially in the face of changing [clinical] evidence." However, due to CMS's desire to maintain</p>	NCQA	X		X	X	X		MU2 Million Hearts

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description*	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			alignment with the EHR Incentive Program, CMS will not make changes to EHR measures until the EHR Incentive Program is able to change this measure. commentsfrombut CMS is not finalizing its proposal to remove the claims, registry and GPRO reporting options for this measure. This measure will continue to be reportable through claims, registry, GPRO (including the Shared Savings Program), as well as EHR in PQRS 2015. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.								
040 9 /20 5		Effective Clinical Care	HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis: Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea and syphilis screenings were performed at least once since the diagnosis of HIV infection Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.	NCQA AMA- PCPI	X					X	
065 1 /25 4		Effective Clinical Care	Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain: Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the	ACEP	X		X				

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description*	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.								
065 2 /25 5		Effective Clinical Care	<p>Rh Immunoglobulin (Rhogam) for Rh-Negative Pregnant Women at Risk of Fetal Blood Exposure: Percentage of Rh-negative pregnant women aged 14-50 years at risk of fetal blood exposure who receive Rh-Immunoglobulin (Rhogam) in the emergency department (ED)</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.</p>	ACEP	X		X				
N/ A /26 8		Effective Clinical Care	<p>Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy: All female patients of childbearing potential (12-44 years old) diagnosed with epilepsy who were counseled about epilepsy and how its treatment may affect contraception and pregnancy at least once a year</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be</p>	AAN	X		X				

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description*	Measure Steward	Claims	CSV	Registry	EHR	GPPO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.								
N/ A/2 70		Effective Clinical Care	<p>Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Sparing Therapy: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have been managed by corticosteroids greater than or equal to 10 mg/day of prednisone equivalents for 60 or greater consecutive days or a single prescription equating to 600mg prednisone or greater for all fills that have been prescribed corticosteroid sparing therapy in the last reporting year</p> <p>Commenters requested this IBD measure and others noted in this table be reportable through registry in addition to the IBD Measure Group to better support providers reporting these measures. CMS agrees, and for this reason CMS is finalizing this measure with modifications as reportable in 2015 PQRS through registry and measure group.</p>	AGA			X			X	
N/ A/2 71		Effective Clinical Care	<p>Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury – Bone Loss Assessment: Percentage of patients aged 18 years and older with an inflammatory bowel disease encounter who were prescribed prednisone equivalents greater than or equal to 10 mg/day for 60 or greater consecutive days or a single prescription equating to 600mg prednisone or greater for all fills and were documented for risk of bone loss once during the reporting year or the previous calendar year</p> <p>Commenters requested this IBD measure and others noted in this table be reportable through registry in addition to the IBD Measure Group to better support providers reporting these measures. CMS agrees, and for this reason CMS is finalizing this measure with modifications as reportable in 2015 PQRS through registry and measure group.</p>	AGA			X			X	
N/ A/2 74		Effective Clinical Care	<p>Inflammatory Bowel Disease (IBD): Testing for Latent Tuberculosis (TB) Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy: Percentage of</p>	AGA			X			X	

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description*	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			<p>patients aged 18 years and older with a diagnosis of inflammatory bowel disease for whom a tuberculosis (TB) screening was performed and results interpreted within six months prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy</p> <p>Commenters requested this IBD measure and others noted in this table be reportable through registry in addition to the IBD Measure Group to better support providers reporting these measures. CMS agrees, and for this reason CMS is finalizing this measure with modifications as reportable in 2015 PQRS through registry and measure group.</p>								
N/ A/2 75		Effective Clinical Care	<p>Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted within one year prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy</p> <p>Commenters requested this IBD measure and others noted in this table be reportable through registry in addition to the IBD Measure Group to better support providers reporting these measures. CMS agrees, and for this reason CMS is finalizing this measure with modifications as reportable in 2015 PQRS through registry and measure group.</p>	AGA			X			X	
065 8 /32 0		Communica tion and Care Coordination	<p>Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients: Percentage of patients aged 50 years and older receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report</p> <p>Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not</p>	AGA ASGE ACG	X		X				

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.								
152 5 /32 6		Effective Clinical Care	Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy: Percentage of patients aged 18 and older with a diagnosis of nonvalvular atrial fibrillation (AF) or atrial flutter whose assessment of the specified thromboembolic risk factors indicate one or more high-risk factors or more than one moderate risk factor, as determined by CHADS ₂ risk stratification, who were prescribed warfarin OR another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism Several commenters were concerned with CMS’ proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.	AMA- PCPI ACCF AHA	X		X				

[¥] Measure details including titles, descriptions and measure owner information may vary during a particular program year. This is due to the timing of measure specification preparation and the measure versions used by the various reporting options/methods. Please refer to the measure specifications that apply for each of the reporting options/methods for specific measure details.

d. PQRS Measures Groups

Section 414.90(b) defines a measures group as a subset of four or more PQRS measures that have a particular clinical condition or focus in common. The denominator definition and coding of the measures group identifies the condition or focus that is shared across the measures within a particular measures group.

In the CY 2014 PFS proposed rule, we proposed (78 FR 43448) to increase the number of measures that may be included in a measures group from a minimum of 4 measures to a minimum

of 6. We proposed increasing the minimum number of measures that may be contained in a measures group in accordance with increasing the number of individual measures to be reported via claims and registry. However, we did not finalize this proposal, stating that, although we still plan to increase the minimum number of measures in a measures group in the future, we would work with the measure developers and owners of these measures groups appropriately to add measures to measures groups that only contain four measures within the measures group (78 FR 74730). For CY 2015, we again we

proposed to modify § 414.90(b) to define a measures group as a subset of six or more PQRS measures that have a particular clinical condition or focus in common (79 FR 40457). We solicited and received the following public comment on this proposal:

Comment: Several commenters opposed this proposal. Commenters noted that CMS did not work with the measure group developers and owners to create the proposed measures groups that consist of at least 6 measures and were concerned that the additional measures in the proposed measures groups were arbitrarily added and not

relevant to the measures already contained in the measures group.

Response: While we understand the commenters' concerns that the additional measures may not be relevant to the measure group topic or condition, we note that we have performed clinical analyses to ensure that the added measures relate to the measure group topics and conditions. The addition of measures within the measures groups was not arbitrary. While some of the measures did not address the specific topic or condition depicted, we added measures within the measures groups that we believed were clinically relevant to report, as we believe these measures address topics and clinical conditions that are accepted in the clinical community as critical to monitor. For example, in most instances, we added measures from the cross-cutting measures set such as Tobacco Screening and Cessation and Medication Reconciliation. With respect to the concern that measures developers and measure owners were not consulted when developing our proposal to add measures to the measures groups, we will continue to work with the measure developers and owners to address any concerns they may have with the final measures groups and address changes when needed through future rulemaking. Based on the reasons stated here and in the proposed rule, we are finalizing our proposal to modify § 414.90(b) to define a measures group as a subset of six or more PQRS measures that have a particular clinical condition or focus in common.

In addition, we proposed to add two new measures groups that will be available for reporting in the PQRS beginning in 2015: The Sinusitis and Acute Otitis Externa (AOE) measures groups (79 FR 40457).

Furthermore, we proposed to remove the following measures groups (79 FR 40457):

- Perioperative care measures group;
- Back pain measures group;
- Cardiovascular prevention measures group;
- Ischemic Vascular Disease (IVD) measures group;
- Sleep Apnea measures group; and
- Chronic obstructive pulmonary disease (COPD) measures group.

We received the following comments on our proposals related to our proposals related to either the proposed addition or removal of the following measures groups:

Comments on the proposed removal of the Perioperative Care Measures Group: Several commenters requested that CMS retain the Perioperative Care Measures Group and the related

individual measures noting the following: "There is a bias in measuring that improves performance; (2) there are few measures applicable to surgeons it will be much harder to participate in PQRS without the perioperative measures."

Response: While there has been evidence to suggest there may be a bias in measuring that improves performance, there is an equal amount of evidence to the contrary that suggest this bias is not impactful. Additionally, we believe that there are a number of broadly applicable measures that these specialty surgeons can report. For these reasons, we are finalizing our proposal to remove the Perioperative Care Measure Group from reporting in 2015 PQRS.

Comments on the proposed removal of the Back Pain Measures Group: Several commenters were concerned with the proposal to remove the Back Pain measures group, noting it would negatively impact physician anesthesiologists', pain medicine physicians' and physical therapists' ability to report. Other commenters supported the removal of some of the Back Pain measure group measures such as "Back Pain: Initial Visit" and "Back Pain: Physical Exam."

Response: The measures in this measure group reflect clinical concepts that do not add clinical value to PQRS. Specifically, the measures in this group are entirely clinical process measures that do not meaningfully contribute to improved patient outcomes, and CMS believes that removal of this measure group will not negatively impact physician anesthesiologists', pain medicine physicians', and physical therapists' ability to report. For these reasons, we are finalizing our proposal to remove the Back Pain Measure Group from reporting in 2015 PQRS.

Comments on the proposed removal of the Cardiovascular Prevention Measures Group: We proposed to remove the cardiovascular prevention measures group because a number of individual measures contained in this measures group are proposed to be removed from all PQRS program reporting options with the exception of EHR reporting. No comments were received about the removal of this measure group. For these reasons, we are finalizing our proposal to remove the Cardiovascular Prevention Measure Group from reporting in 2015 PQRS.

Comments on the proposed removal of the Ischemic Vascular Disease Measures Group: We proposed to remove the cardiovascular prevention measures group because a number of individual measures contained in this

measures group are proposed to be removed from all PQRS program reporting options with the exception of EHR reporting. No comments were received about the removal of this measure group. For these reasons, we are finalizing our proposal to remove the Ischemic Vascular Disease Measure Group from reporting in 2015 PQRS.

Comments on the proposed addition of the Acute Otitis Externa (AOE) Measures Group: One commenter supported the addition of this measure group.

Response: We did not receive any dissenting comments. For these reasons, we are finalizing our proposal to include the AOE measure group for reporting in 2015 PQRS.

Comments on the proposed removal of the Chronic Obstructive Pulmonary Disorder (COPD) Measures Group: We initially proposed to remove this measure group contingent on the measure steward not being able to maintain certain measures contained in this measures group (79 FR 40457). A new steward has been identified for the measures at risk, and for this reason we are not finalizing our proposal to remove this measures group in 2015.

Comments on the proposed removal of the Sleep Apnea Measures Group: We initially proposed to remove this measures group contingent on the measure steward not being able to maintain certain measures contained in this measures group. A new steward has been identified for the measures at risk, and for this reason we are not finalizing our proposal to remove this measures group in 2015.

Comments on the proposed Rheumatoid Arthritis Measures Group: Commenters disagreed with CMS's proposal to add the Preventive Care and Screening: Influenza Immunization (PQRS #110) and Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (PQRS #226) measures to the Rheumatoid Arthritis Measures Group for CY 2015. Commenters did not believe these measures provide substantial value to the specific clinical focus of this measures group. Instead, commenters recommend the addition of cross-cutting measure Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow (PQRS #128) and Pain Assessment and Follow-up (PQRS #131) to achieve the goal of six measures while retaining clinical relevance. CMS agrees with commenters' suggestions and thus is not finalizing the proposal to add PQRS #110 and #226 to this measure group, but rather will add PQRS #128 and #131 to better support the clinical purpose of this measure

group while meeting the six measure minimum requirement.

Tables 57 through 79 specify our final measures groups in light of the reasons stated in the proposed rule and the

comments received. Please note that some measures groups were not addressed above. With respect to the measures groups that were not

addressed above, we did not receive any comments on these proposed measures groups and are therefore finalizing the respective measures groups as proposed.

TABLE 57—ASTHMA MEASURES GROUP FOR 2015 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
0047/053	Asthma: Pharmacologic Therapy for Persistent Asthma—Ambulatory Care Setting: Percentage of patients aged 5 through 64 years with a diagnosis of persistent asthma who were prescribed long-term control medication.	AMA-PCPI/NCQA
0041/110	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	AMA-PCPI
0419/130	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	CMS/QIP
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	AMA-PCPI
N/A/402	Tobacco Use and Help with Quitting Among Adolescents: Percentage of adolescents 13 to 20 years of age with a primary care visit during the measurement period for whom tobacco use status was documented and received help quitting if identified as a tobacco user.	NCQA/NCIQM
0421/128	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous six months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous six months of the encounter. Normal Parameters: Age 65 years and older BMI ≥ 23 and < 30 kg/m ² ; Age 18—64 years BMI ≥ 18.5 and < 25 kg/m ² .	CMS/QIP

TABLE 58—ACUTE OTITIS EXTERNA (AOE) MEASURES GROUP FOR 2015 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
0653/091	Acute Otitis Externa (AOE): Topical Therapy: Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	AMA-PCPI
0654/093	Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy—Avoidance of Inappropriate Use: Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	AMA-PCPI
0419/130	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	CMS/QIP
0420/131	Pain Assessment and Follow-Up: Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	CMS/QIP
0101/154	Falls: Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	AMA-PCPI
0101/155	Falls: Plan of Care: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	AMA-PCPI
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	AMA-PCPI
N/A/317	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	CMS/QIP

TABLE 59—CATARACTS MEASURES GROUP FOR 2015 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
0419/130	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	CMS/QIP
0565/191	Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery: Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved within 90 days following the cataract surgery.	AMA-PCPI/NCQA
0564/192	Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures: Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence.	AMA-PCPI/NCQA
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	AMA-PCPI
N/A/303	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery: Percentage of patients aged 18 years and older in sample who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey.	AAO
N/A/304	Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery: Percentage of patients aged 18 years and older in sample who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey.	AAO
N/A/388	Cataract Surgery with Intra-Operative Complications (Unplanned Rupture of Posterior Capsule Requiring Unplanned Vitrectomy): Rupture of the posterior capsule during anterior segment surgery requiring vitrectomy.	AAECEE/ACHS
N/A/389	Cataract Surgery: Difference Between Planned and Final Refraction: Percentage of patients who achieve planned refraction within +/- 1.0 D.	AAECEE/ACHS

TABLE 60—CHRONIC KIDNEY DISEASE (CKD) MEASURES GROUP FOR 2015 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
0326/047	Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	AMA-PCPI/NCQA
0041/110	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	AMA-PCPI
1668/121	Adult Kidney Disease: Laboratory Testing (Lipid Profile): Percentage of patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) who had a fasting lipid profile performed at least once within a 12-month period.	AMA-PCPI
N/A/122	Adult Kidney Disease: Blood Pressure Management: Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) and proteinuria with a blood pressure < 140/90 mmHg OR ≥ 140/90 mmHg with a documented plan of care.	AMA-PCPI
0419/130	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	CMS/QIP
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	AMA-PCPI

TABLE 61—CHRONIC OBSTRUCTIVE PULMONARY DISORDER (COPD) MEASURES GROUP FOR 2015 AND BEYOND

[Please note that CMS initially proposed to remove this measure group contingent on the measure steward not being able to maintain certain measures contained in this measures group. A new steward has been identified for the measures at risk and for this reason CMS is not finalizing its proposal to remove this measures group in 2015.]

NQF/PQRS	Measure title and description	Measure developer
0326/047	Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	AMA-PCPI/NCQA
0091/051	Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation: Percentage of patients aged 18 years and older with a diagnosis of COPD who had spirometry evaluation results documented.	AMA-PCPI
0102/052	Chronic Obstructive Pulmonary Disease (COPD): Inhaled Bronchodilator Therapy: Percentage of patients aged 18 years and older with a diagnosis of COPD and who have an FEV1/FVC less than 60% and have symptoms who were prescribed an inhaled bronchodilator.	AMA-PCPI
0041/110	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	AMA-PCPI
0043/111	Pneumonia Vaccination Status for Older Adults: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	NCQA
0419/130	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	CMS/QIP
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	AMA-PCPI

TABLE 62—CORONARY ARTERY BYPASS GRAFT (CABG) MEASURES GROUP FOR 2015 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
0134/043	Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG Surgery: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who received an IMA graft.	STS
0236/044	Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery: Percentage of isolated Coronary Artery Bypass Graft (CABG) surgeries for patients aged 18 years and older who received a beta-blocker within 24 hours prior to surgical incision.	CMS/QIP
0129/164	Coronary Artery Bypass Graft (CABG): Prolonged Intubation: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation > 24 hours.	STS
0130/165	Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who, within 30 days postoperatively, develop deep sternal wound infection involving muscle, bone, and/or mediastinum requiring operative intervention.	STS
0131/166	Coronary Artery Bypass Graft (CABG): Stroke: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have a postoperative stroke (that is, any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours.	STS
0114/167	Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure: Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis.	STS
0115/168	Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason. Please note that CMS had proposed to remove this measure from the program and thus this measure group as a result in the NPRM. However, as noted above in Table 55, CMS is not finalizing its proposal to remove this measure, and as such, the measure is not being removed from this measure group either..	STS

TABLE 63—CORONARY ARTERY DISEASE (CAD) MEASURES GROUP FOR 2015 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
0067/006	Coronary Artery Disease (CAD): Antiplatelet Therapy: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who were prescribed aspirin or clopidogrel.	AMA-PCPI/ACCF/AHA

TABLE 63—CORONARY ARTERY DISEASE (CAD) MEASURES GROUP FOR 2015 AND BEYOND—Continued

NQF/PQRS	Measure title and description	Measure developer
0070/007	Coronary Artery Disease (CAD): Beta-Blocker Therapy—Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have prior MI OR a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	AMA-PCPI
0421/128	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous six months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous six months of the encounter. Normal Parameters: Age 65 years and older BMI ≥ 23 and < 30 kg/m ² ; Age 18–64 years BMI ≥ 18.5 and < 25 kg/m ² .	CMS/QIP
0419/130	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	CMS/QIP
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	AMA-PCPI
N/A/242	Coronary Artery Disease (CAD): Symptom Management: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period with results of an evaluation of level of activity and an assessment of whether anginal symptoms are present or absent with appropriate management of anginal symptoms within a 12 month period.	AMA-PCPI/ACCF/AHA

TABLE 64—DEMENTIA MEASURES GROUP FOR 2015 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
0326/047	Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	AMA-PCPI/NCQA
N/A/280	Dementia: Staging of Dementia: Percentage of patients, regardless of age, with a diagnosis of dementia whose severity of dementia was classified as mild, moderate or severe at least once within a 12 month period.	AMA-PCPI
N/A/281	Dementia: Cognitive Assessment: Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12 month period.	AMA-PCPI
N/A/282	Dementia: Functional Status Assessment: Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of functional status is performed and the results reviewed at least once within a 12 month period.	AMA-PCPI
N/A/283	Dementia: Neuropsychiatric Symptom Assessment: Percentage of patients, regardless of age, with a diagnosis of dementia and for whom an assessment of neuropsychiatric symptoms is performed and results reviewed at least once in a 12 month period.	AMA-PCPI
N/A/284	Dementia: Management of Neuropsychiatric Symptoms: Percentage of patients, regardless of age, with a diagnosis of dementia who have one or more neuropsychiatric symptoms who received or were recommended to receive an intervention for neuropsychiatric symptoms within a 12 month period.	AMA-PCPI
N/A/285	Dementia: Screening for Depressive Symptoms: Percentage of patients, regardless of age, with a diagnosis of dementia who were screened for depressive symptoms within a 12 month period.	AMA-PCPI
N/A/286	Dementia: Counseling Regarding Safety Concerns: Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled or referred for counseling regarding safety concerns within a 12 month period.	AMA-PCPI
N/A/287	Dementia: Counseling Regarding Risks of Driving: Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled regarding the risks of driving and the alternatives to driving at least once within a 12 month period.	AMA-PCPI
N/A/288	Dementia: Caregiver Education and Support: Percentage of patients, regardless of age, with a diagnosis of dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND referred to additional sources for support within a 12 month period.	AMA-PCPI

TABLE 65—DIABETES MEASURES GROUP FOR 2015 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
0059/001	Diabetes: Hemoglobin A1c Poor Control: Percentage of patients 18–75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	NCQA
0041/110	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	AMA-PCPI

TABLE 65—DIABETES MEASURES GROUP FOR 2015 AND BEYOND—Continued

NQF/PQRS	Measure title and description	Measure developer
0055/117	Diabetes: Eye Exam: Percentage of patients 18 through 75 years of age with a diagnosis of diabetes (type 1 and type 2) who had a retinal or dilated eye exam in the measurement period or a negative retinal or dilated eye exam (negative for retinopathy) in the year prior to the measurement period.	NCQA
0062/119	Diabetes: Medical Attention for Neuropathy: The percentage of patients 18–75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	NCQA
0056/163	Diabetes: Foot Exam: Percentage of patients aged 18–75 years of age with diabetes who had a foot exam during the measurement period.	NCQA
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	AMA-PCPI

TABLE 66—GENERAL SURGERY MEASURES GROUP FOR 2015 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
0419/130	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	CMS/QIP
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	AMA-PCPI
N/A/354	Anastomotic Leak Intervention: Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery.	ACS
N/A/355	Unplanned Reoperation within the 30 Day Postoperative Period: Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.	ACS
N/A/356	Unplanned Hospital Readmission within 30 Days of Principal Procedure: Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	ACS
N/A/357	Surgical Site Infection (SSI): Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	ACS
N/A/358	Patient-Centered Surgical Risk Assessment and Communication: Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	ACS

TABLE 67—HEART FAILURE (HF) MEASURES GROUP FOR 2015 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
0081/005	Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD): Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge.	AMA-PCPI/ACCF/AHA
0083/008	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD): Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge.	AMA-PCPI/ACCF/AHA
0326/047	Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	AMA-PCPI/NCQA
0041/110	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization..	AMA-PCPI
0419/130	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	CMS/QIP
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	AMA-PCPI

TABLE 68—HEPATITIS C MEASURES GROUP FOR 2015 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
0395/084	Hepatitis C: Ribonucleic Acid (RNA) Testing Before Initiating Treatment: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who started antiviral treatment within the 12 month reporting period for whom quantitative hepatitis C virus (HCV) RNA testing was performed within 12 months prior to initiation of antiviral treatment.	AMA-PCPI
0396/085	Hepatitis C: HCV Genotype Testing Prior to Treatment: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who started antiviral treatment within the 12 month reporting period for whom hepatitis C virus (HCV) genotype testing was performed within 12 months prior to initiation of antiviral treatment.	AMA-PCPI
0398/087	Hepatitis C: Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Testing Between 4–12 Weeks After Initiation of Treatment: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom quantitative hepatitis C virus (HCV) RNA testing was performed between 4–12 weeks after the initiation of antiviral treatment.	AMA-PCPI
0419/130	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	CMS/QIP
0399/183	Hepatitis C: Hepatitis A Vaccination in Patients with Hepatitis C Virus (HCV): Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who have received at least one injection of hepatitis A vaccine, or who have documented immunity to hepatitis A.	AMA-PCPI
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	AMA-PCPI
N/A/401	Screening for Hepatocellular Carcinoma (HCC) in patients with Hepatitis C Cirrhosis: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12 month reporting period.	AGA/AASLD/AMA-PCPI
N/A/390	Discussion and Shared Decision Making Surrounding Treatment Options: Percentage of patients aged 18 years and older with a diagnosis of hepatitis C with whom a physician or other qualified healthcare professional reviewed the range of treatment options appropriate to their genotype and demonstrated a shared decision making approach with the patient. To meet the measure, there must be documentation in the patient record of a discussion between the physician or other qualified healthcare professional and the patient that includes all of the following: treatment choices appropriate to genotype, risks and benefits, evidence of effectiveness, and patient preferences toward treatment.	AGA/AASLD/AMA-PCPI

TABLE 69—HIV/AIDS MEASURES GROUP FOR 2015 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
0326/047	Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	AMA-PCPI/NCQA
0418/134	Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan: Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	CMS/QIP
0405/160	HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis: Percentage of patients aged 6 weeks and older with a diagnosis of HIV/AIDS who were prescribed Pneumocystis Jiroveci Pneumonia (PCP) prophylaxis.	NCQA
0409/205	HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis: Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea and syphilis screenings were performed at least once since the diagnosis of HIV infection.	AMA-PCPI/NCQA
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	AMA-PCPI
2082/338	HIV Viral Load Suppression: The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	HRSA
2083/339	Prescription of HIV Antiretroviral Therapy: Percentage of patients, regardless of age, with a diagnosis of HIV prescribed antiretroviral therapy for the treatment of HIV infection during the measurement year.	HRSA
2079/340	HIV Medical Visit Frequency: Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.	HRSA

TABLE 70—INFLAMMATORY BOWEL DISEASE (IBD) MEASURES GROUP FOR 2015 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
0041/110	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	AMA-PCPI
0043/111	Pneumonia Vaccination Status for Older Adults: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	NCQA
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	AMA-PCPI
N/A/270	Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Sparing Therapy: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have been managed by corticosteroids greater than or equal to 10 mg/day of prednisone equivalents for 60 or greater consecutive days or a single prescription equating to 600 mg prednisone or greater for all fills that have been prescribed corticosteroid sparing therapy in the last reporting year.	AGA
N/A/271	Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury—Bone Loss Assessment: Percentage of patients aged 18 years and older with an inflammatory bowel disease encounter who were prescribed prednisone equivalents greater than or equal to 10 mg/day for 60 or greater consecutive days or a single prescription equating to 600 mg prednisone or greater for all fills and were documented for risk of bone loss once during the reporting year or the previous calendar year.	AGA
N/A/274	Inflammatory Bowel Disease (IBD): Testing for Latent Tuberculosis (TB) Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease for whom a tuberculosis (TB) screening was performed and results interpreted within 6 months prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy.	AGA
N/A/275	Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted within 1 year prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy.	AGA

TABLE 71—ONCOLOGY MEASURES GROUP FOR 2015 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
0387/071	Breast Cancer: Hormonal Therapy for Stage IC–IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer: Percentage of female patients aged 18 years and older with Stage IC through IIIC, ER or PR positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period.	AMA-PCPI/ASCO/NCCN
0385/072	Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients: Percentage of patients aged 18 through 80 years with AJCC Stage III colon cancer who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy within the 12-month reporting period.	AMA-PCPI/ASCO/NCCN
0041/110	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	AMA-PCPI
0419/130	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	CMS/QIP
0384/143	Oncology: Medical and Radiation—Pain Intensity Quantified: Percentage of patients, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	AMA-PCPI
0383/144	Oncology: Medical and Radiation—Plan of Care for Pain: Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	AMA-PCPI
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	AMA-PCPI

TABLE 72—OPTIMIZING PATIENT EXPOSURE TO IONIZING RADIATION MEASURES GROUP FOR 2015 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
N/A/359	Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging Description: Percentage of computed tomography (CT) imaging reports for all patients, regardless of age, with the imaging study named according to a standardized nomenclature and the standardized nomenclature is used in institution's computer systems.	AMA-PCPI

TABLE 72—OPTIMIZING PATIENT EXPOSURE TO IONIZING RADIATION MEASURES GROUP FOR 2015 AND BEYOND—Continued

NQF/PQRS	Measure title and description	Measure developer
N/A/360	Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies: Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study.	AMA-PCPI
N/A/361	Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry: Percentage of total computed tomography (CT) studies performed for all patients, regardless of age, that are reported to a radiation dose index registry AND that include at a minimum selected data elements.	AMA-PCPI
N/A/362	Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT) Images Available for Patient Follow-up and Comparison Purposes: Percentage of final reports for computed tomography (CT) studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available to non-affiliated external entities on a secure, media free, reciprocally searchable basis with patient authorization for at least a 12-month period after the study.	AMA-PCPI
N/A/363	Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Imaging Studies Through a Secure, Authorized, Media-Free, Shared Archive: Percentage of final reports of computed tomography (CT) studies performed for all patients, regardless of age, which document that a search for Digital Imaging and Communications in Medicine (DICOM) format images was conducted for prior patient CT imaging studies completed at non-affiliated external healthcare facilities or entities within the past 12-months and are available through a secure, authorized, media free, shared archive prior to an imaging study being performed.	AMA-PCPI
N/A/364	Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines: Percentage of final reports for CT imaging studies of the thorax for patients aged 18 years and older with documented follow-up recommendations for incidentally detected pulmonary nodules (for example, follow-up CT imaging studies needed or that no follow-up is needed) based at a minimum on nodule size AND patient risk factors.	AMA-PCPI

TABLE 73—PARKINSON'S DISEASE MEASURES GROUP FOR 2015 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
0326/047	Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	AMA-PCPI/NCQA
N/A/289	Parkinson's Disease: Annual Parkinson's Disease Diagnosis Review: All patients with a diagnosis of Parkinson's disease who had an annual assessment including a review of current medications (for example, medications that can produce Parkinson-like signs or symptoms) and a review for the presence of atypical features (for example, falls at presentation and early in the disease course, poor response to levodopa, symmetry at onset, rapid progression [to Hoehn and Yahr stage 3 in 3 years], lack of tremor or dysautonomia) at least annually.	AAN
N/A/290	Parkinson's Disease: Psychiatric Disorders or Disturbances Assessment: All patients with a diagnosis of Parkinson's disease who were assessed for psychiatric disorders or disturbances (for example, psychosis, depression, anxiety disorder, apathy, or impulse control disorder) at least annually.	AAN
N/A/291	Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment: All patients with a diagnosis of Parkinson's disease who were assessed for cognitive impairment or dysfunction at least annually.	AAN
N/A/292	Parkinson's Disease: Querying about Sleep Disturbances: All patients with a diagnosis of Parkinson's disease (or caregivers, as appropriate) who were queried about sleep disturbances at least annually.	AAN
N/A/293	Parkinson's Disease: Rehabilitative Therapy Options: All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (for example, physical, occupational, or speech therapy) discussed at least annually.	AAN
N/A/294	Parkinson's Disease: Parkinson's Disease Medical and Surgical Treatment Options Reviewed: All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate) who had the Parkinson's disease treatment options (for example, non-pharmacological treatment, pharmacological treatment, or surgical treatment) reviewed at least once annually.	AAN

TABLE 74—PREVENTIVE CARE MEASURES GROUP FOR 2015 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
0046/039	Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older who have a central dual-energy X-ray absorptiometry (DXA) measurement ordered or performed at least once since age 60 or pharmacologic therapy prescribed within 12 months.	AMA-PCPI/NCQA
N/A/48	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	AMA-PCPI/NCQA
0041/110	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	AMA-PCPI
0043/111	Pneumonia Vaccination Status for Older Adults: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	NCQA
N/A/112	Breast Cancer Screening: Percentage of women 50 through 74 years of age who had a mammogram to screen for breast cancer within 27 months.	NCQA
0034/113	Colorectal Cancer Screening: Percentage of patients 50 through 75 years of age who had appropriate screening for colorectal cancer.	NCQA
0421/128	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous six months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous six months of the current encounter. Normal Parameters: Age 65 years and older BMI ≥ 23 and < 30 kg/m ² ; Age 18–64 years BMI ≥ 18.5 and < 25 kg/m ² .	CMS/QIP
0418/134	Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan: Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	CMS/QIP
AQA Adopt- ed/173.	Preventive Care and Screening: Unhealthy Alcohol Use—Screening: Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use at least once within 24 months using a systematic screening method**. Please note that CMS had proposed to remove this measure from the program and thus this measure group as a result in the NPRM. However, as noted above in Table 55, CMS is not finalizing its proposal to remove this measure, and as such, the measure is not being removed from this measure group either..	AMA-PCPI
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	AMA-PCPI

TABLE 75—RHEUMATOID ARTHRITIS (RA) MEASURES GROUP FOR 2015 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
0054/108	Rheumatoid Arthritis (RA): Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy: Percentage of patients aged 18 years and older who were diagnosed with RA and were prescribed, dispensed, or administered at least one ambulatory prescription for a disease-modifying anti-rheumatic drug (DMARD).	NCQA
0421/128	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous six months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous six months of the current encounter. Normal Parameters: Age 65 years and older BMI ≥ 23 and < 30 kg/m ² ; Age 18–64 years BMI ≥ 18.5 and < 25 kg/m ² .	CMS/QIP
0420/131	Pain Assessment and Follow-Up: Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	CMS/QIP
N/A/176	Rheumatoid Arthritis (RA): Tuberculosis Screening: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 6 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD).	AMA-PCPI
N/A/177	Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease activity within 12 months.	AMA-PCPI
N/A/178	Rheumatoid Arthritis (RA): Functional Status Assessment: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	AMA-PCPI
N/A/179	Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease prognosis at least once within 12 months.	AMA-PCPI

TABLE 75—RHEUMATOID ARTHRITIS (RA) MEASURES GROUP FOR 2015 AND BEYOND—Continued

NQF/PQRS	Measure title and description	Measure developer
N/A/180	Rheumatoid Arthritis (RA): Glucocorticoid Management: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	AMA-PCPI

TABLE 76—SINUSITIS MEASURES GROUP FOR 2015 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
0419/130	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	CMS/QIP
0420/131	Pain Assessment and Follow-Up: Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	CMS/QIP
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	AMA-PCPI
N/A/331	Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Appropriate Use): Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 7 days of diagnosis or within 10 days after onset of symptoms.	AMA-PCPI
N/A/332	Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin Prescribed for Patients with Acute Bacterial Sinusitis: Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulante, as a first line antibiotic at the time of diagnosis.	AMA-PCPI
N/A/333	Adult Sinusitis: Computerized Tomography for Acute Sinusitis (Overuse): Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	AMA-PCPI

TABLE 77—SLEEP APNEA MEASURES GROUP FOR 2015 AND BEYOND

[Please note that CMS initially proposed to remove this measure group contingent on the measure steward not being able to maintain certain measures contained in this measures group. A new steward has been identified for the measures at risk and for this reason CMS is not finalizing its proposal to remove this measures group in 2015.]

NQF/PQRS	Measure title and description	Measure developer
0421/128	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous six months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous six months of the current encounter. Normal Parameters: Age 65 years and older BMI ≥ 23 and < 30 kg/m ² ; Age 18–64 years BMI ≥ 18.5 and < 25 kg/m ² .	CMS/QIP
0419/130	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	CMS/QIP
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	AMA-PCPI
N/A/276	Sleep Apnea: Assessment of Sleep Symptoms: Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea that includes documentation of an assessment of sleep symptoms, including presence or absence of snoring and daytime sleepiness.	AMA-PCPI/NCQA
N/A/277	Sleep Apnea: Severity Assessment at Initial Diagnosis: Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	AMA-PCPI/NCQA
N/A/278	Sleep Apnea: Positive Airway Pressure Therapy Prescribed: Percentage of patients aged 18 years and older with a diagnosis of moderate or severe obstructive sleep apnea who were prescribed positive airway pressure therapy.	AMA-PCPI/NCQA
N/A/279	Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy: Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	AMA-PCPI/NCQA

TABLE 78—TOTAL KNEE REPLACEMENT (TKR) MEASURES GROUP FOR 2015 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
0419/130	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	CMS/QIP
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	AMA-PCPI
N/A/350	Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy: Percentage of patients regardless of age or gender undergoing a total knee replacement with documented shared decision-making with discussion of conservative (non-surgical) therapy (for example, NSAIDS, analgesics, weight loss, exercise, injections) prior to the procedure.	AAHKS
N/A/351	Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation: Percentage of patients regardless of age or gender undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (for example, history of Deep Vein Thrombosis, Pulmonary Embolism, Myocardial Infarction, Arrhythmia and Stroke) and Stroke.	AAHKS
N/A/352	Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet: Percentage of patients regardless of age undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet.	AAHKS
N/A/353	Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report: Percentage of patients regardless of age or gender undergoing total knee replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of the prosthetic implant and the size of prosthetic implant.	AAHKS

e. Measures Available for Reporting in the GPRO Web Interface

We finalized the measures that are available for reporting in the GPRO web interface for 2014 and beyond in the CY 2013 PFS final rule (77 FR 69269). However, we proposed to remove and add measures in the GPRO web interface measure set as reflected in Tables 47 and 48 in the CY 2015 PFS proposed rule for 2015 and beyond (79 FR 40468). Specifically, Table 47 specified the measures we proposed to remove for reporting from the GPRO web interface, and Table 48 specified

the measures we proposed to add for reporting in the GPRO web interface. CMS proposed to adopt Depression Remission at Twelve Months (NQF #0710) in the 2015 GPRO Web Interface reporting option for ACOs and group practices (79 FR 40469). This measure is currently reportable in the PQRS program through the EHR reporting option only and has not been tested using claims level data or sampling methodology. Depression Remission at Twelve Months (NQF #0710) requires a look-back period and a look-forward period possibly spanning multiple calendar years. Additionally, this

measure requires utilization of a PHQ-9 depression screening tool with a score greater than 9 and a diagnosis of depression/dysthymia to identify the beginning of the episode (initial patient population). Successful completion of the quality action for this measure looks for a PHQ-9 score of less than 5 at the twelve month mark (plus or minus 30 days) from the initial onset of the episode. CMS solicited comments regarding these proposals, and the comments are addressed in Tables 79 and 80.

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**TABLE 79: Measures Being Removed from the Group Practice Reporting Option Web Interface
Beginning in 2015 and Beyond**

NQF/ PQRS	GPRO Module	NQS Domain	Measure and Title Description [†]	Measure Steward	Other Quality Reporting Programs
Measures Finalized as Proposed					
0097/ 046	Care Coordination/ Patient Safety	Patient Safety	<p>Medication Reconciliation: Percentage of patients aged 65 years and older discharged from any inpatient facility (for example, hospital, skilled nursing facility, or rehabilitation facility) and seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care who had a reconciliation of the discharge medications with the current medication list in the outpatient medical record documented</p> <p>Several commenters agreed with CMS' proposal to remove this measure, noting "full medication reconciliation should be done at least annually with all patients." However, other commenters disagreed, indicating this measure "specifically evaluates the medication reconciliation during a time period when patients are most vulnerable during a time of transitions of care that may result in adverse consequences to the patient including preventable readmission to the hospital." However, CMS continues to believe NQF #0419 Documentation of Medications in the Medical Record is a more robust and broadly applicable measure. Furthermore, there have been implementation issues with this measure in the web interface, despite CMS believing this is a valuable measure. Finally, CMS is continuing to work to align the GPRO with the EHR Incentive Programs, and NQF #0419 is in the Incentive Program, whereas PQRS #046 is not. For these reasons, CMS is finalizing its proposal to remove this measure from reporting through the GPRO WI in 2015 PQRS and the Shared Savings Program.</p>	AMA- PCPI/ NCQA	
0074/ 197	Coronary Artery Disease	Effective Clinical Care	<p>Coronary Artery Disease (CAD): Lipid Control: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who have a LDL-C result < 100 mg/dL OR patients who have a LDL-C result ≥ 100 mg/dL and have a documented plan of care to achieve LDL-C < 100 mg/dL, including at a minimum the prescription of a statin</p> <p>While some commenters disagreed with CMS's proposal to remove this measure "unless or until new measures that are more consistent with new and existing guidelines are put in place to replace them", several commenters supported the proposal to retire this and the two other lipid control measures listed as a result of new clinical guidelines released in 2013 by the American College of Cardiology and American Heart Association. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS and the Shared Savings Program.</p>	AMA- PCPI/ ACCF/ AHA	

NQF/ PQRS	GPRO Module	NQS Domain	Measure and Title Description ^y	Measure Steward	Other Quality Reporting Programs
0729/ 319	Diabetes Mellitus	Effective Clinical Care	<p>Diabetes Composite: Optimal Diabetes Care: Patients ages 18 through 75 with a diagnosis of diabetes, who meet all the numerator targets of this composite measure:</p> <ul style="list-style-type: none"> • Diabetes Mellitus: High Blood Pressure Control. • Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control. • Diabetes Mellitus: Hemoglobin A1c Control (< 8%). • Diabetes Mellitus: Tobacco Non-Use <p>CMS proposed retiring 4 components of the 5 part diabetes composite measure as noted above. Specifically, commenters:</p> <ul style="list-style-type: none"> • Disagreed with removing the blood pressure component, noting “important that diabetic patients have their blood pressure and cholesterol monitored in order to prevent co-morbidities; if assessing quality of their care is folded into the general Medicare patient population, the focus on their care and desirable health care outcomes is effectively “watered down.” However, other commenters supported this change noting “a measure that is based on a specific A1c level is no longer an accurate measure of a physician’s ability to provide high quality care for their patients.” CMS agrees this measure may no longer be the best measure of quality care in this area. Further, CMS continues to believe this measure is somewhat duplicative of the measure Controlling High Blood Pressure (NQF #0018) and that the diabetes measure may capture a subpopulation of the broader Controlling High Blood Pressure measure. • Agreed with removing the LDL component as a result of new clinical guidelines released in 2013 by the American College of Cardiology and American Heart Association (https://circ.ahajournals.org/content/early/2013/11/11/01.cir.000.0437738.63853.7a.full.pdf). • Agreed with removing the Hemoglobin A1c Control (<8%) component, noting it is “too restrictive for a small cohort of patients and not restrictive enough for the majority of patients.” • Disagreed with removing the Tobacco Non-Use component, noting “this outcome based measure (as opposed to the screening and counseling measure) is not only a critical measure for diabetic best management, but removing it is stepping away from a known shared goal of moving towards outcome based measures.” However, other commenters supported this change noting that this measure, in addition to other measures, “were either duplicative of other measures or the guidelines for the measure have been changed.” CMS continues to believe this component is somewhat duplicative of the Tobacco Screening and Cessation Counseling measure (NQF 0028) and NQF 0028 is more broadly applicable. For these reasons, CMS is finalizing its proposal to remove these four components of the diabetes composite measure from reporting in 2015 PQRS and the Shared Savings Program. 	MNCM	

NQF/ PQRS	GPRO Module	NQS Domain	Measure and Title Description ^y	Measure Steward	Other Quality Reporting Programs
0075/ 241	Ischemic Vascular Disease	Effective Clinical Care	<p>Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL-C Control (< 100 mg/dL): Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had each of the following during the measurement period: a complete lipid profile and LDL-C was adequately controlled (< 100 mg/dL)</p> <p>Commenters supported the proposal to retire this lipid control related measure because of the new clinical guidelines for statin treatment, as discussed for other LDL measures in this table. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS and the Shared Savings Program.</p>	NCQA	MU2 Million Hearts
Measures Not Finalized as Proposed					
0068/ 204	Ischemic Vascular Disease	Effective Clinical Care	<p>Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic: Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period and who had documentation of use of aspirin or another antithrombotic during the measurement period</p> <p>CMS received comments about this measure being proposed for removal from the Web Interface for PQRS and the Shared Savings Program. Some commenters requested clarification of CMS's previous concern that the measure may not align with current guidelines when proposing its removal. After reviewing the measure further, we have determined the measure does not conflict with current guidelines the updated ATP-4 cholesterol guidelines, which have gone away from focusing on specific LDL targets, but do not impact this measure as previously thought. This measure is also a core measure for the Million Hearts Initiative. It is CMS's intent to maintain alignment with other quality reporting programs and HHS Initiatives. CMS also received comments supporting the removal of the measure from the Shared Savings Program, but requesting clarification of guideline changes impacting the measure. Therefore, CMS will maintain alignment with the Million Hearts program and for this reason CMS is retaining this measure and it will be available for reporting through the GPRO WI in 2015 PQRS and the Shared Savings Program.</p>	NCQA	MU2 Million Hearts

NQF/ PQRS	GPRO Module	NQS Domain	Measure and Title Description ^y	Measure Steward	Other Quality Reporting Programs
0729/ 319	Diabetes Mellitus	Effective Clinical Care	<p>Diabetes Composite: Optimal Diabetes Care: Patients ages 18 through 75 with a diagnosis of diabetes, who meet all the numerator targets of this composite measure:</p> <ul style="list-style-type: none"> • Diabetes Mellitus: Daily Oral Aspirin or Antiplatelet Medication Use for Patients with Diabetes and Ischemic Vascular Disease <p>CMS did not originally propose to remove this measure. However, this measure was reported in the PQRS as a component of the diabetes composite reportable via the GPRO Web Interface. We note that, while we did not originally propose to remove this measure, we proposed to remove all of the other components of the diabetes composite of which this measure was a part. Specifically, we proposed to remove the following components of the diabetes composite:</p> <ul style="list-style-type: none"> • Diabetes Mellitus: High Blood Pressure Control. • Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control. • Diabetes Mellitus: Hemoglobin A1c Control (< 8%). • Diabetes Mellitus: Tobacco Non-Use <p>Since we proposed to remove all other components of the diabetes composite listed above, we believe the public could reasonably foresee that we would remove this measure from the PQRS and Shared Savings Program measure set if all other components of the diabetes composite were removed. In addition, CMS believes the Daily Oral Aspirin component of this measure may be somewhat duplicative of PQRS #204 (Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic). Therefore, we are removing this measure from the PQRS measure set.</p> <p>To maintain alignment with PQRS and reduce reporting burden for ACOs, we are also removing this measure from the Shared Savings Program measure set. CMS believes that removing this measure will reduce burden on ACOs and allow them to improve their performance on the diabetes composite by reducing the number of measures included in the composite. Therefore, for the reasons stated above, we are removing this measure from the PQRS and Shared Savings Program measure set beginning in 2015</p>	MNCM	

TABLE 80: New Measures That Will Be Available for Reporting by the Group Practice Reporting Option Web Interface Beginning in 2015 and Beyond

NQE/ PQRS	GPRO Module	NQS Domain	Measure and Title Description [¶]	Measure Steward	Other Quality Reporting Programs
Measures Finalized as Proposed					
0059/ 001	Diabetes Mellitus	Effective Clinical Care	<p>Diabetes: Hemoglobin A1c Poor Control: Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period</p> <p>The Shared Savings Program and PQRS received many comments supporting removal of the Diabetes: Hemoglobin A1c control (<8 percent) (ACO-22), since <8 percent seems restrictive. CMS received some comments suggesting we move toward more outcome measures than process measures. CMS is finalizing its proposal to include this measure in the new Diabetes Management (DM) composite as a more appropriate A1c component for reporting in 2015 PQRS and the Shared Savings Program. This measure, Hemoglobin A1c Poor Control is being finalized because it addresses a clinically important area for diabetic patients and replaces the previous measure in the DM composite.</p>	NCQA	MU2
0055/ 117	Diabetes Mellitus	Effective Clinical Care	<p>Diabetes: Eye Exam: Percentage of patients 18 through 75 years of age with a diagnosis of diabetes (type 1 and type 2) who had a retinal or dilated eye exam by an eye care professional in the measurement period or a negative retinal or dilated eye exam (negative for retinopathy) in the year prior to the measurement period</p> <p>Several commenters supported the addition of this measure to the GPRO WI for PQRS and the Shared Savings Program, noting eye exams are an important part of quality care for diabetic patients. CMS also received some comments suggesting that we not finalize additional process measures and questioning the improvement to outcomes, noting while “foot and eye exams are an important part of good diabetes care, we recommend that they not replace the current outcomes measures in the Diabetes Composite measure set.” CMS agrees foot and eye exams are a valuable addition that reflect good diabetes care. Please see Table 79 for additional discussion of the rationale for the removal of the previous diabetes composite. CMS is finalizing its proposal to include this measure in the new Diabetes Management composite in the GPRO WI for reporting in 2015 PQRS and Shared Savings Program due to the clinical importance of the measure and alignment of programs.</p>	NCQA	MU2

NQF/ PQRS	GPRO Module	NQS Domain	Measure and Title Description [¶]	Measure Steward	Other Quality Reporting Programs
0419/ 130	Care Coordinati on/ Patient Safety	Patient Safety	<p>Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list <i>must</i> include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND <i>must</i> contain the medications' name, dosage, frequency and route of administration</p> <p>While some commenters disagreed with the addition of this measure, others suggested medication reconciliation should be performed at all office visits and not just those visits occurring after an inpatient discharge. Furthermore, the steward of CARE-1 (PQRS #46) Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility indicated this measure is not appropriate for the GPRO WI reporting mechanism. Some commenters recommended limiting documentation of current medications to only the last visit due to potential reporting burden.</p> <p>We disagree with the commenters who disagree with the addition of this measure. We believe this measure adequately captures an important aspect of patient safety – the need to understand a patient's current medications. We believe documenting current medications is key to determining the most appropriate care for a patient. With respect to the commenters who believed that medication reconciliation should be performed on all office visits, please note that the title and description of the measure does not limit this measure to documentation after an inpatient discharge. With respect to a measure steward's concern that this measure is not appropriate for the GPRO WI reporting mechanism, we disagree with the measure steward. As we note above, we believe this measure is appropriate for the GPRO WI as it captures an important aspect of patient safety.</p> <p>Based on the comments received and for the reasons stated above, CMS is finalizing its proposal to replace PQRS #46 with PQRS #130 Documentation of Current Medications in the Medical Record for reporting in the GPRO WI in 2015 PQRS and Shared Savings Program and will consider reporting burden in finalizing specifications for GPRO reporting.</p>	CMS/Q IP	MU2

NQF/ PQRS	GPRO Module	NQS Domain	Measure and Title Description ^y	Measure Steward	Other Quality Reporting Programs
0710/ 370	Mental Health	Effective Clinical Care	<p>Depression Remission at Twelve Months: Adult patients age 18 and older with major depression or dysthymia and an initial PHQ-9 score > 9 who demonstrate remission at twelve months defined as PHQ-9 score less than 5. This measure applies to both patients with newly diagnosed and existing depression whose current PHQ-9 score indicates a need for treatment.</p> <p>Several commenters for PQRS and the Shared Savings Program expressed concern over use of the PHQ-9, indicating not all practices use this tool. CMS appreciates commenter feedback and concerns regarding issues with the use of PHQ-9. CMS recognizes there may be EPs reporting who do not currently use this tool and because of the look back period may not be able to implement this tool in time for the next reporting period, and as such CMS is considering adjustments to how this measure will be reported, specifically for the Shared Savings Program. CMS continues to believe this Depression Remission measure represents an important outcome. Depression management is particularly important due the effects on patient adherence with treatment for other chronic conditions. For these reasons, CMS is finalizing its proposal to make this measure reportable through the GPRO WI in 2015 PQRS and the Shared Savings Program. Given the comments and concerns raised regarding the use of the PHQ-9 tool and providing ACOs with time to make necessary adjustments for implementation, the measure will be designated as pay-for-reporting under the Shared Savings Program for all 3 years of an ACO's first agreement period, as specified in the program's final measure set.</p>	MNCM	MU2
Measures Not Finalized as Proposed					
0067/ 006	Coronary Artery Disease	Effective Clinical Care	<p>Coronary Artery Disease (CAD): Antiplatelet Therapy: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12 month period who were prescribed aspirin or clopidogrel.</p> <p>Commenters agreed with the addition of this measure, but recommended testing the composite and maintaining as only pay-for-reporting for the Shared Savings Program. Other commenters did not agree with including this measure due to concerns that the composite has not been reviewed by NQF and has not been tested before implementation. CMS agrees this measure needs to be tested as part of the composite prior to implementation and as such, CMS is not finalizing its proposal to include this measure for reporting in for the PQRS GPRO web interface and Shared Savings Program.</p>	AMA- PCPI/ ACCF/ AHA	MU2

NQF/ PQRS	GPRO Module	NQS Domain	Measure and Title Description [¶]	Measure Steward	Other Quality Reporting Programs
0070/ 007	Coronary Artery Disease	Effective Clinical Care	<p>Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%): Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have prior MI OR a current or LVEF < 40% who were prescribed beta-blocker therapy</p> <p>Some commenters agreed with the addition of this measure while others did not agree with including this measure and suggested testing and submission to NQF. We also believe this measure is topped out. Therefore, CMS is not finalizing its proposal to include this measure for reporting for the PQRS and Shared Savings Program GPRO web interface.</p>	AMA- PCPI/ ACCF/ AHA	MU2
0056/ 163	Diabetes Mellitus	Effective Clinical Care	<p>Diabetes: Foot Exam: Percentage of patients aged 18-75 years of age with diabetes who had a foot exam during the measurement period</p> <p>While several commenters supported the addition of this measure, many commenters did not support the inclusion of this process measure and suggested further testing of the composite as well as identifying the link to improved outcomes. Furthermore, CMS believes the measures that are being finalized for the Diabetes Composite represent a robust, outcome focused set of measures with room for quality improvement. Therefore, CMS is not finalizing its proposal to make this measure reportable through the GPRO WI in 2015 PQRS and the Shared Savings Program.</p>	NCQA	MU2
N/A/ 242	Coronary Artery Disease	Effective Clinical Care	<p>Coronary Artery Disease (CAD): Symptom Management: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12 month period with results of an evaluation of level of activity and an assessment of whether anginal symptoms are present or absent with appropriate management of anginal symptoms within a 12 month period</p> <p>Some commenters agreed with CMS' proposal to include this measure in the GPRO WI. However, most commenters did not support including the measure due to lack of NQF endorsement and the reporting burden/challenges if the measure is finalized. Due to the comments received not supporting the measure due to reporting burden, CMS is not finalizing its proposal to include this measure for reporting in 2015 PQRS and Shared Savings Program GPRO web interface.</p>	AMA- PCPI/ ACCF/ AHA	

NQF/ PQRS	GPRO Module	NQS Domain	Measure and Title Description [¶]	Measure Steward	Other Quality Reporting Programs
0729/ 319	Diabetes Mellitus	Effective Clinical Care	<p>Diabetes Composite: Optimal Diabetes Care: Patients ages 18 through 75 with a diagnosis of diabetes, who meet all the numerator targets of this composite measure:</p> <ul style="list-style-type: none"> • Diabetes Mellitus: Daily Oral Aspirin or Antiplatelet Medication Use for Patients with Diabetes and Ischemic Vascular Disease <p>As discussed in Table 79 above, CMS believes the Daily Oral Aspirin component of this measure may be somewhat duplicative of PQRS #204, ACO-30 (Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic). Furthermore, upon further review and with CMS's intent to maintain alignment with other quality reporting programs and limit the number of potentially duplicative measures that may cause additional reporting burden, CMS is removing this measure from the PQRS and Shared Savings Program measure sets.</p>	MNCM	

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f. The Clinician Group (CG) Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey

In the CY 2014 PFS final rule with comment period, we finalized the CG-CAHPS survey available for reporting under the PQRS for 2014 and beyond (78 FR 74750 through 74751), to which we are now referring as the CAHPS for PQRS. Please note that, in the CY 2014 PFS final rule with comment period, we classified the CAHPS for PQRS survey under the care coordination and communication NQS domain. We noted that this was an error on our part, as the CAHPS for PQRS survey has typically been classified under the Person and Caregiver-Centered Experience and Outcomes domain as the CAHPS for PQRS survey assesses beneficiary experience of care and outcomes. Therefore, as we indicated in Table 21 of the CY 2015 proposed rule, we proposed to reclassify the CAHPS for PQRS survey under the Person and Caregiver-Centered Experience and Outcomes domain. We invited public comment on this proposal. Please note that the comments on this proposal are addressed in Table 54, where the domain change for CAHPS for PQRS as well as other PQRS measures is indicated.

6. Statutory Requirements and Other Considerations for the Selection of PQRS Quality Measures for Meeting the Criteria for Satisfactory Participation in a QCDR for 2014 and Beyond for Individual Eligible Professionals

For the measures which eligible professionals participating in a QCDR

must report, section 1848(m)(3)(D) of the Act, as amended and added by section 601(b) of the ATRA, provides that the Secretary shall treat eligible professionals as satisfactorily submitting data on quality measures if they satisfactorily participate in a QCDR. Section 1848(m)(3)(E) of the Act, as added by section 601(b) of the ATRA, provides some flexibility with regard to the types of measures applicable to satisfactory participation in a QCDR, by specifying that for measures used by a QCDR, sections 1890(b)(7) and 1890A(a) of the Act shall not apply, and measures endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act may be used.

In the CY 2014 PFS final rule with comment period, we finalized requirements related to the parameters for the measures that would have to be reported to CMS by a QCDR for the purpose of its individual eligible professionals meeting the criteria for satisfactory participation under the PQRS (78 FR 74751 through 74753). Although we did not propose to remove any of the requirements we finalized related to these parameters, we proposed to modify the following parameters we finalized in the CY 2014 PFS final rule with comment period related to measures that may be reported by a QCDR (79 FR 40472 through 40473):

- The QCDR must have at least 1 outcome measure available for reporting, which is a measure that assesses the results of health care that are experienced by patients (that is, patients' clinical events; patients' recovery and health status; patients'

experiences in the health system; and efficiency/cost).

As we proposed that for an eligible professional to meet the criterion for satisfactory participation in a QCDR for the 2017 PQRS payment adjustment, the eligible professional must report on at least 3 outcome measures or, in lieu of 3 outcome measures, at least 2 outcome measures and 1 resource use, patient experience of care, or efficiency/appropriate use measure, we modified this requirement to conform to this satisfactory participation criterion. Therefore, we proposed that a QCDR must have at least 3 outcome measures available for reporting, which is a measure that assesses the results of health care that are experienced by patients (that is, patients' clinical events; patients' recovery and health status; patients' experiences in the health system; and efficiency/cost). In lieu of having 3 outcome measures available for reporting, the QCDR must have at least 2 outcome measures available for reporting and at least 1 resource use, patient experience of care, or efficiency/appropriate use measure (79 FR 40473). We solicited and received the following comments on this proposal:

Comment: As the majority of commenters opposed our proposal to require the reporting of 3 outcomes measures to meet the criteria for satisfactory participation for the 2017 PQRS payment adjustment, for the same reasons, the majority of commenters also opposed our proposal to require that a QCDR must have at least 3 outcome measures available for reporting, or, in lieu of 3 outcome measures, a QCDR have at least 2

outcome measures available for reporting and at least 1 resource use, patient experience of care, or efficiency/appropriate use measure. The commenters believed this proposed requirement was overly burdensome for QCDRs.

Response: We responded to the commenters' concerns regarding our proposal to require the reporting of 3 outcome measures to meet the criteria for satisfactory participation for the 2017 PQRS payment adjustment at III.K.3.a. For the same reasons discussed in that section, we are modifying our proposal to require that a QCDR must have at least 3 outcome measures available for reporting, or, in lieu of 3 outcome measures, a QCDR have at least 2 outcome measures available for reporting and at least 1 resource use, patient experience of care, or efficiency/appropriate use measure. To correspond with the final criteria for the satisfactory participation for the 2017 PQRS payment adjustment, for 2015 and beyond, we are modifying this proposal to require that a QCDR have at least 2 outcome measures available for reporting. An outcome measure is a measure that assesses the results of health care that are experienced by patients (that is, patients' clinical events; patients' recovery and health status; patients' experiences in the health system; and efficiency/cost). In lieu of having 2 outcomes measures available for reporting, the QCDR must at least have 1 outcome measure available for reporting and at least 1 resource use, patient experience of care, efficiency/appropriate use measure, or patient safety measure. We believe this is an appropriate modification, as QCDRs that only have the ability to report 1 outcome measure may still report 1 outcome measure as long as the QCDR has another measure (resource use, patient experience of care, efficiency/appropriate use measure, or patient safety measure) in another domain available for reporting.

We proposed to define resource use, patient experience of care, or efficiency/appropriate use measures in the following manner (79 FR 40473):

- A resource use measure is a measure that is a comparable measure of actual dollars or standardized units of resources applied to the care given to a specific population or event, such as a specific diagnosis, procedure, or type of medical encounter. We did not receive any comments on this proposed definition of a resource use measure. As such, we are finalizing this definition of a resource use measure as proposed.

- A patient experience of care measure is a measure of person- or

family-reported experiences (outcomes) of being engaged as active members of the health care team and in collaborative partnerships with providers and provider organizations. We did not receive any comments on this proposed definition of a patient experience of care measure as proposed.

- An efficiency/appropriate use measure is a measure of the appropriate use of health care services (such as diagnostics or therapeutics) based upon evidence-based guidelines of care, or for which the potential for harm exceeds the possible benefits of care. We did not receive any comments this proposed definition of an efficiency/appropriate use measure. As such, we are finalizing this definition of an efficiency/appropriate use measure as proposed.

Please note that, for purposes of meeting the criteria for satisfactory participation in a QCDR, we allow QCDRs to report on any measure if it meets the measure parameters we finalize. We noted that we would allow and encourage the reporting of the Consumer Assessment of Healthcare Providers Surgical Care Survey (S-CAHPS) through a QCDR.

Finally, in the CY 2014 PFS final rule with comment period, we stated that a QCDR must provide to CMS descriptions and narrative specifications for the measures for which it will report to CMS by no later than March 31, 2014. In keeping with this timeframe, we proposed that a QCDR must provide to CMS descriptions for the measures for which it will report to CMS for a particular year by no later than March 31 of the applicable reporting period for which the QCDR wishes to submit quality measures data. We solicited and received the following comments on this proposal:

Comment: Commenters believed that it was reasonable to require a QCDR to provide to CMS descriptions and narrative specifications for the measures for which it will report to CMS by no later than March 31, 2014.

Response: We appreciate the commenters' feedback. Based on the comments received, we are finalizing our proposal to require that a QCDR must provide to CMS descriptions for the measures for which it will report to CMS for a particular year by no later than March 31 of the applicable reporting period for which the QCDR wishes to submit quality measures data. For example, if a QCDR wishes to submit quality measures data for the 2017 PQRS payment adjustment (the 12-month reporting period of which occurs in 2015), the QCDR must provide to

CMS descriptions for the measures for which it will report to CMS by no later than March 31, 2015. The descriptions must include: name/title of measures, NQF # (if NQF-endorsed), descriptions of the denominator, numerator, and when applicable, denominator exceptions and denominator exclusions of the measure. The narrative specifications provided must be similar to the narrative specifications we provide in our measures list, available at http://www.cms.gov/apps/ama/license.asp?file=PQRS/downloads/2014_PQRS_IndClaimsRegistry_MeasureSpecs_SupportingDocs_12132013.zip.

Related to this proposal, we proposed that, 15 days following CMS approval of these measure specifications, the QCDR must publicly post the measures specifications for the measures it intends to report for the PQRS using any public format it prefers. Immediately following posting of the measures specification information, the QCDR must provide CMS with the link to where this information is posted. CMS will then post this information when it provides its list of QCDRs for the year. We believe providing this information will further aid in creating transparency of reporting. We solicited and received the following comment on this proposal:

Comment: Some commenters supported this proposal, as the commenters believe it was reasonable to require that this information be made available to the public. The commenters supported our proposal to defer to the QCDR in terms of what platform and in what manner this data may be made available to the public. Some commenters opposed this proposal based on their concerns that the public reporting requirement was overly burdensome and urged CMS to delay requiring the posting of measures data until the measures have been tested for validity and reliability. The commenters believed that CMS should not make substantial changes in the QCDR requirements, as the QCDR option is new and the entities need time to familiarize themselves with the QCDR option before new requirements are established. One commenter preferred public reporting of QCDR quality measures data through a single site so that information would be easily accessible and people seeking this information would not be forced to look through multiple sites.

Response: With respect to the commenters who opposed this proposal and urged us not to make additional changes to the QCDR option while entities become more familiar with this option, we understand the commenters'

concerns. However, we believe that transparency of data is a key component of a QCDR option. Furthermore, in the CY 2014 PFS final rule, while we did not finalize our proposal that a QCDR have a plan to publicly report quality measures data, we noted that we encouraged QCDRs “to move towards the public reporting of quality measures data” and stated that “[w]e plan to establish such a requirement in the future and will revisit this proposed requirement as part of CY 2015 rulemaking” (78 FR 74471). Therefore, we believe that QCDRs were on notice that we would finalize a requirement to make quality measures data available to the public. With respect to the commenter that preferred this information to be posted on a single site, we note that the Physician Compare Web site will provide quality measures data information on eligible professionals participating in QCDRs. Therefore, while the QCDRs are free to provide this information elsewhere, the Physician Compare Web site will serve as a point where all information will be accessible. Based on the reasons we stated above and in the proposed rule, we are finalizing our proposal to require that, 15 days following CMS approval of these measure specifications, a QCDR must publicly post the measures specifications for the measures it intends to report for the PQRS using any public format it prefers. Immediately following posting of the measures specification information, the QCDR must provide CMS with the link to where this information is posted. CMS will then post this information when it provides its list of QCDRs for the year.

7. Informal Review

In the CY 2013 PFS final rule with comment period (77 FR 69289), we established that “an eligible professional electing to utilize the informal review process must request an informal review by February 28 of the year in which the payment adjustment is being applied. For example, if an eligible professional requests an informal review related to the 2015 payment adjustment, the eligible professional would be required to submit his/her request for an informal review by February 28, 2015.” As stated in the CY 2013 PFS final rule with comment period, we believed this deadline provided ample time for eligible professionals and group practices after their respective claims begin to be adjusted due to the payment adjustment. However, because PQRS data is used to establish the quality composite of the VM, we believe it is necessary to expand the informal review

process to allow for some limited corrections of the PQRS data to be made. Therefore, we proposed to modify the payment adjustment informal review deadline to within 30 days of the release of the feedback reports. For example, if the feedback reports for the 2016 payment adjustment (based on data collected for 2014 reporting periods) were released on August 31, 2015, an eligible professional or group practice would be required to submit a request for an informal review by September 30, 2015. We believe that by being able to notify eligible professionals and group practices of CMS’ decision on the informal review request much earlier than we would have been able to do with the previous informal review request deadline we can provide a brief period for an eligible or group practice to make some limited corrections to its PQRS data. This resubmitted data could then be used to make corrections to the VM calculations, when appropriate.

The PQRS regulations at § 414.90(m)(1) currently require an eligible professional or group practice to submit an informal review request to CMS within 90 days of the release of the feedback reports. Therefore, we proposed to revise § 414.90(m)(1) to require the request of the informal review within 30 days of release of the feedback reports.

Regarding the eligible professional’s or group practice’s ability to provide additional information to assist in the informal review process, we proposed to provide the following limitations as to what information might be taken into consideration:

- CMS would only allow resubmission of data that was submitted using a third-party vendor using the qualified registry, EHR data submission vendor, or QCDR reporting mechanisms. Therefore, CMS would not allow resubmission of data submitted via claims, direct EHR, or the GPRO web interface reporting mechanisms. We are limiting resubmission to third-party vendors, because we believe that third-party vendors are more easily able to detect errors than direct users.

- CMS would only allow resubmission of data that was already previously submitted to CMS. Submission of new data—such as new measures data not previously submitted or new data for eligible professionals for which data was not submitted during the original submission period—would not be accepted.

- For any given resubmission period, CMS would only accept data that was previously submitted for the reporting periods for which the corresponding

informal review period applies. For example, the resubmission period immediately following the informal review period for the 2017 PQRS payment adjustment would only allow resubmission for data previously submitted for the 2017 PQRS payment adjustment reporting periods occurring in 2015.

As such, we proposed to add § 414.90(m)(3) to reflect this proposal as follows: (3) If, during the informal review process, CMS finds errors in data that was submitted using a third-party vendor using either the qualified registry, EHR data submission vendor, or QCDR reporting mechanisms, CMS may allow for the resubmission of data to correct these errors. (i) CMS will not allow resubmission of data submitted via claims, direct EHR, and the GPRO web interface reporting mechanisms. (ii) CMS will only allow resubmission of data that was already previously submitted to CMS. (iii) CMS will only accept data that was previously submitted for the reporting periods for which the corresponding informal review period applies.

We invited public comment on these proposals. The following is summary of the comments we received regarding on these proposals.

Comment: Several commenters opposed our proposal to change the amount of time an eligible professional or group practice would have to submit an informal review request to 30 days. One commenter stated that it was necessary to have a longer timeframe, as accessing PQRS feedback reports can be extremely cumbersome and time-intensive. The commenters believed that 30 days was an insufficient amount of time to access, analyze, and identify errors in the PQRS feedback reports. Some of these commenters urged CMS to extend the request period to 60 or 90 days in lieu of 30 days.

Response: We understand that this provides eligible professionals and group practices with a much shorter timeline with which to submit an informal review request. We also understand the commenters’ concerns regarding having to access and analyze the feedback reports as well as submitting an informal review request within 30 days. As we stated in the proposed rule, it is necessary to shorten the timeline in order to be allow for the resubmission of data, if applicable to the eligible professional or group practice. However, given these concerns, we will increase the amount of time in which eligible professionals and group practices may submit an informal review request. In order to finalize our proposal to allow for the resubmission

of data, it is necessary to receive all informal review requests within 60 days of the release of the feedback reports. At this time, we believe the 60-day deadline still provides us with enough time to allow for the resubmission of data. However, should we find that more time is needed to process resubmissions, we reserve the right to propose further changes to this deadline in future rulemaking. Therefore, for the reasons stated above and in the proposed rule, we are finalizing our proposal to modify § 414.90(m)(1) to indicate the payment adjustment informal review deadline to within 60 days of the release of the feedback reports beginning in 2015.

Comment: Several commenters generally supported our proposal to allow for resubmission of data.

Response: We appreciate the commenters' support for this proposal. Based on the support for this proposal and for the reasons we stated in the proposed rule, we are finalizing our proposal to allow for resubmission of data as proposed. As we proposed, we are providing the following limitations as to what information might be taken into consideration:

- CMS would only allow resubmission of data that was submitted by a third-party vendor on behalf of an eligible professional or group practice using the qualified registry, EHR data submission vendor, or QCDR reporting mechanisms. Therefore, CMS would not allow resubmission of data submitted via claims, direct EHR, or the GPRO web interface reporting mechanisms. We are limiting resubmission to third-party vendors, because we believe that third-party vendors are more easily able to detect errors than direct users.

- CMS would only allow resubmission of data that was already previously submitted to CMS. Submission of new data—such as new measures data not previously submitted or new data for eligible professionals for which data was not submitted during the original submission period—would not be accepted.

- For any given resubmission period, CMS would only accept data that was previously submitted for the reporting periods for which the corresponding informal review period applies. For example, the resubmission period immediately following the informal review period for the 2017 PQRS payment adjustment would only allow resubmission for data previously submitted for the 2017 PQRS payment adjustment reporting periods occurring in 2015.

Because of the comments received and for the reasons stated above and in

the proposed rule, we are finalizing our proposal to modify the payment adjustment informal review deadline to within 60 days of the release of the feedback reports. In addition, to allow resubmission of data, we are finalizing our proposal, as proposed, to add § 414.90(m)(3) as follows: (3) If, during the informal review process, CMS finds errors in data that was submitted using a third-party vendor using either the qualified registry, EHR data submission vendor, or QCDR reporting mechanisms, CMS may allow for the resubmission of data to correct these errors. (i) CMS will not allow resubmission of data submitted via claims, direct EHR, and the GPRO web interface reporting mechanisms. (ii) CMS will only allow resubmission of data that was already previously submitted to CMS. (iii) CMS will only accept data that was previously submitted for the reporting periods for which the corresponding informal review period applies.

L. Electronic Health Record (EHR) Incentive Program

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes incentive payments under Medicare and Medicaid for the adoption and meaningful use of certified EHR technology (CEHRT). Section 1848(o)(2)(B)(iii) of the Act requires that in selecting CQMs for eligible professionals (EPs) to report under the EHR Incentive Program, and in establishing the form and manner of reporting, the Secretary shall seek to avoid redundant or duplicative reporting otherwise required. As such, we have taken steps to establish alignments among various quality reporting and payment programs that include the submission of CQMs.

For CY 2012 and subsequent years, § 495.8(a)(2)(ii) requires an EP to successfully report the clinical quality measures selected by CMS to CMS or the states, as applicable, in the form and manner specified by CMS or the states, as applicable.

In the CY 2014 PFS final rule with comment period (78 FR 74756), we finalized our proposal to require EPs who seek to report CQMs electronically under the Medicare EHR Incentive Program to use the most recent version of the electronic specifications for the CQMs and have CEHRT that is tested and certified to the most recent version of the electronic specifications for the CQMs. We noted it is important for EPs to electronically report the most recent versions of the electronic specifications for the CQMs as updated measure versions correct minor inaccuracies

found in prior measure versions. We stated that to ensure that CEHRT products can successfully transmit CQM data using the most recent version of the electronic specifications for the CQMs, it is important that the product be tested and certified to the most recent version of the electronic specifications for the CQMs.

Since finalizing this proposal, we have received feedback from stakeholders regarding the difficulty and expense of having to test and recertify CEHRT products to the most recent version of the electronic specifications for the CQMs. Although we still believe EPs should test and certify their products to the most recent version of the electronic specifications for the CQMs when feasible, we understand the burdens associated with this requirement. Therefore, to eliminate this added burden, we proposed that, beginning in CY 2015, EPs would not be required to ensure that their CEHRT products are recertified to the most recent version of the electronic specifications for the CQMs. Please note that, although we are not requiring recertification, EPs must still report the most recent version of the electronic specifications for the CQMs.

In the CY 2014 PFS final rule with comment period, we established the requirement that EPs who seek to report CQMs electronically under the Medicare EHR Incentive Program must use the most recent version of the electronic specifications for the CQMs (78 FR 74756). We solicited and received the following public comments on these proposals:

Comment: The majority of commenters supported our proposal not to require EPs to recertify their EHR products to the most recent version of the eCQMs. One commenter opposed this proposal, stating that if we did not require recertification some products run the risk of not being able to perform critical Stage 2 functions such as secure messaging between patients and providers, offering patients the ability to view, download, and transmit their own health information, and improving care transitions with a summary of care record for transitions and referrals.

Response: We appreciate the commenters' support for this proposal. With respect to the commenter who opposed this proposal, we agree that it is important to recertify as frequently as possible for the reasons the commenter stated. However, at this time, we understand that requiring recertification to the most recent version of the electronic specifications for the CQMs, which could occur annually, may be overly burdensome and time-consuming

for providers. Please note that this proposal was limited to EPs and not intended to apply to eligible hospitals (EHs) or critical access hospitals. Based on the comments received and for the reasons stated in the proposed rule, we are finalizing our proposal that, beginning in CY 2015, EPs are not required to ensure that their CEHRT products are recertified to the most recent version of the electronic specifications for the CQMs. Although we are not requiring recertification, EPs must still report the most recent version of the electronic specifications for the CQMs.

Additionally, we noted in the proposed rule that, with respect to the following measure CMS140v2, Breast Cancer Hormonal Therapy for Stage IC–IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer (NQF 0387), a substantive error was discovered in the June 2013 version of this electronically specified clinical quality measure (79 FR 40474). If an EP chooses to report this measure electronically under the EHR Incentive Program in CY 2014, the prior, December 2012 version of the measure, which is CMS140v1, must be used (78 FR 74757). In the proposed rule (79 FR 40474), we stated that because a more recent and corrected version of this measure has been developed, we will require the reporting of the most recent, updated version of the measure Breast Cancer Hormonal Therapy for Stage IC–IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer (NQF 0387), if an EP chooses to report the measure electronically in CY 2015.

In the EHR Incentive Program Stage 2 final rule, we established CQM reporting options for the Medicare EHR Incentive Program for CY 2014 and subsequent years that include one individual reporting option that aligns with the PQRS's EHR reporting option (77 FR 54058) and two group reporting options that align with the PQRS GPRO and Medicare Shared Savings Program (MSSP) and Pioneer ACOs (77 FR 54076 to 54078). In the CY 2014 PFS final rule with comment period, we finalized two additional aligned options for EPs to report CQMs for the Medicare EHR Incentive Program for CY 2014 and subsequent years with the intention of minimizing the reporting burden on EPs (78 FR 74753 through 74757). One of the aligned options finalized in the CY 2014 PFS final rule with comment period (78 FR 74754 through 74755) is a reporting option for CQMs for the Medicare EHR Incentive Program under which EPs can submit CQM information using qualified clinical data registries, according the definition and

requirements for qualified clinical data registries established under the PQRS.

The second aligned option finalized in the CY 2014 PFS final rule with comment period (78 FR 74755 through 74756) is a group reporting option for CQMs for the Medicare EHR Incentive Program beginning in CY 2014 under which EPs who are part of a Comprehensive Primary Care (CPC) initiative practice site that successfully reports at least nine electronically specified CQMs across three domains for the relevant reporting period in accordance with the requirements established for the CPC initiative and using CEHRT would satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program. If a CPC practice site is not successful in reporting, EPs who are part of the site would still have the opportunity to report CQMs in accordance with the requirements established for the Medicare EHR Incentive Program in the Stage 2 final rule. Additionally, only those EPs who are beyond their first year of demonstrating meaningful use may use this CPC group reporting option. The CPC practice sites must submit the CQM data in the form and manner required by the CPC initiative. Therefore, whether CPC required electronic submission or attestation of CQMs, the CPC practice site must submit the CQM data in the form and manner required by the CPC initiative.

The CPC initiative, under the authority of section 3021 of the Affordable Care Act, is a multi-payer initiative fostering collaboration between public and private health care payers to strengthen primary care. Under this initiative, we will pay participating primary care practices a care management fee to support enhanced, coordinated services. Simultaneously, participating commercial, state, and other federal insurance plans are also offering enhanced support to primary care practices that provide high-quality primary care. There are approximately 483 CPC practice sites across 7 health care markets in the U.S. More details on the CPC initiative can be found at <http://innovation.cms.gov/initiatives/Comprehensive-Primary-Care-Initiative/index.html>.

Under the CPC initiative, CPC practice sites are required to report to CMS a subset of the CQMs that were selected in the EHR Incentive Program Stage 2 final rule for EPs to report under the EHR Incentive Program beginning in CY 2014 (for a list of CQMs that were selected in the EHR Incentive Program Stage 2 final rule for EPs to report under

the EHR Incentive Program beginning in CY 2014, see 77 FR 54069 through 54075). We proposed to retain the group reporting option for CPC practice sites as finalized in the CY 2014 PFS final rule, but to relax the requirement for the CQMs to cover three domains. Instead, we proposed that, for CY 2015 only, under this group reporting option, the CPC practice site must report a minimum of nine CQMs from the CPC subset, and the nine CQMs reported must cover at least 2 domains, although we strongly encouraged practice sites to report across more domains if feasible. Although the requirement to report across three domains is important because the domains are linked to the National Quality Strategy and used throughout CMS quality programs, the CPC practice sites are required to report from a limited number of CQMs that were selected for the EHR Incentive Program and are focused on a primary care population. Therefore, these CPC practice sites may not have measures to select from that cover three domains. Additionally, CPC practice sites are assessed for quality performance on measures other than electronically specified CQMs which do cover other National Quality Strategy domains. We invited public comment on this proposal.

The following is a summary of the comments we received regarding our proposal on the group reporting option for CPC practice sites.

Comment: A few commenters indicated general support for relaxing the domain requirement for the primary care physicians, indicating providers should be able to select the measures most applicable to their population.

Response: We appreciate the support for this proposal. The CPC CQM set targets a primary care patient population and therefore is appropriate for reporting by CPC practice sites in the model.

Comment: One commenter opposed relaxing the reporting requirements for CPC practice sites to only report 2 domains instead of 3. The commenter indicated consumers and purchasers want to see measures across these domains reported electronically. The commenter believed CPC practice sites have sufficient measures to choose from to report 9 measures that cover 3 domains.

Response: The CPC initiative is a model tested by the Center for Medicare and Medicaid Innovation. As such, CPC includes specific quality measure reporting requirements for each CPC practice site to be eligible to participate in any Medicare shared savings, which is a component of the model. The

quality reporting requirements include reporting on a subset of the CQMs selected for the EHR Incentive Program beginning in CY 2014.

The CPC measure subset includes a total of 11 measures, of which 7 fall in the clinical process/effectiveness domain, 3 in the population health domain, and 1 in the safety domain. We proposed to reduce the number of domains required to at least 2 domains to allow CPC practice sites that would be unable to obtain in their EHR the one safety CQM in the CPC measure subset to meet the MU CQM requirement. This would provide CPC practice sites an opportunity to successfully report to the CPC model and satisfy the CQM reporting component of meaningful use, so they would not have to report quality measures twice to both CPC and the Medicare EHR Incentive Program.

After consideration of the comments received, and for the reasons stated previously, we are finalizing the proposal to reduce the required number of domains for CY 2015 only as proposed.

M. Medicare Shared Savings Program

Under section 1899 of the Act, CMS has established the Medicare Shared Savings program (Shared Savings Program) to facilitate coordination and cooperation among providers to improve the quality of care for Medicare Fee-For-Service (FFS) beneficiaries and reduce the rate of growth in health care costs. Eligible groups of providers and suppliers, including physicians, hospitals, and other health care providers, may participate in the Shared Savings Program by forming or participating in an Accountable Care Organization (ACO). The final rule implementing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Shared Savings Program: Accountable Care Organizations Final Rule (76 FR 67802)).

Section 1899(b)(3)(A) of the Act requires the Secretary to determine appropriate measures to assess the quality of care furnished by ACOs, such as measures of clinical processes and outcomes; patient, and, wherever practicable, caregiver experience of care; and utilization such as rates of hospital admission for ambulatory sensitive conditions. Section 1899(b)(3)(B) of the Act requires ACOs to submit data in a form and manner specified by the Secretary on measures that the Secretary determines necessary for ACOs to report to evaluate the quality of care furnished by ACOs. Section 1899(b)(3)(C) of the Act requires the Secretary to establish quality performance standards to assess

the quality of care furnished by ACOs, and to seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for the purposes of assessing the quality of care. Additionally, section 1899(b)(3)(D) of the Act gives the Secretary authority to incorporate reporting requirements and incentive payments related to the PQRS, EHR Incentive Program and other similar initiatives under section 1848 of the Act. Finally, section 1899(d)(1)(A) of the Act states that an ACO is eligible to receive payment for shared savings, if they are generated, only after meeting the quality performance standards established by the Secretary.

In the November 2011 final rule establishing the Shared Savings Program, we established the quality performance standards that ACOs must meet to be eligible to share in savings that are generated (76 FR 67870 through 67904). Quality performance measures are submitted by ACOs through a CMS web interface, currently the group practice reporting option (GPRO) web interface, calculated by CMS from internal and claims data, and collected through a patient and caregiver experience of care survey.

Consistent with the directive under section 1899(b)(3)(C) of the Act, we believe the existing Shared Savings Program regulations incorporate a built in mechanism for encouraging ACOs to improve care over the course of their 3-year agreement period, and to reward quality improvement over time. During the first year of the agreement period, ACOs can qualify for the maximum sharing rate by completely and accurately reporting all quality measures. After that, ACOs must meet certain thresholds of performance, which are currently phased in over the course of the ACO's first agreement period, and are rewarded for improved performance on a sliding scale in which higher levels of quality performance translate to higher rates of shared savings (or, for ACOs subject to performance-based risk that demonstrate losses, lower rates of shared losses). In this way, the quality performance standard increases over the course of the ACO's agreement period.

Additionally, we have made an effort to align quality performance measures, submission methods, and incentives under the Shared Savings Program with the PQRS. Eligible professionals participating in an ACO may qualify for the PQRS incentive payment under the Shared Savings Program or avoid the downward PQRS payment adjustment when the ACO satisfactorily reports the

ACO GPRO measures on their behalf using the GPRO web interface.

Since the November 2011 final rule establishing the Shared Savings Program was issued, we have revisited certain aspects of the quality performance standard in the annual PFS rulemaking out of a desire to ensure thoughtful alignment with the agency's other quality incentive programs that are addressed in that rule. Specifically, we have updated our rules to align with PQRS and the EHR Incentive Program, and addressed issues related to benchmarking and scoring ACO quality performance (77 FR 69301 through 69304; 78 FR 74757 through 74764). This year, as part of the CY 2015 Physician Fee Schedule proposed rule, we addressed several issues related to the Shared Savings Program quality performance standard and alignment with other CMS quality initiatives. Specifically, we revisited the current quality performance standard, proposed changes to the quality measures, and sought comment on future quality performance measures. We also proposed to modify the timeframe between updates to the quality performance benchmarks, to establish an additional incentive to reward ACO quality improvement, and to make several technical corrections to the regulations in subpart F of Part 425.

1. Existing Quality Measures and Performance Standard

As discussed previously, section 1899(b)(3)(C) of the Act states that the Secretary may establish quality performance standards to assess the quality of care furnished by ACOs and "seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both. . . ." In the November 2011 Shared Savings Program final rule, we established a quality performance standard that consists of 33 measures. These measures are submitted by the ACO through the GPRO web interface, calculated by CMS from administrative and claims data, and collected via a patient experience of care survey based on the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS) survey. Although the patient experience of care survey used for the Shared Savings Program includes the core CG-CAHPS modules, this patient experience of care survey also includes some additional modules. Therefore, we will refer to the patient experience of care survey that is used under the Shared Savings Program as CAHPS for ACOs. The measures span four domains, including patient experience of care,

care coordination/patient safety, preventive health, and at-risk population. The measures collected through the GPRO web interface are also used to determine whether eligible professionals participating in an ACO qualify for the 2013 and 2014 PQRS incentive payment or avoid the PQRS payment adjustment for 2015 and subsequent years. Eligible professionals in an ACO may qualify for the PQRS incentive payment or avoid the downward PQRS payment adjustment when the ACO satisfactorily reports all of the ACO GPRO measures on their behalf using the GPRO web interface.

In selecting the 33 measure set, we balanced a wide variety of important considerations. Given that many ACOs were expected to be newly formed organizations, in the November 2011 Shared Savings Program final rule (76 FR 67886), we concluded that ACO quality measures should focus on discrete processes and short-term measurable outcomes derived from administrative claims and limited medical record review facilitated by a CMS-provided web interface to lessen the burden of reporting. Because of the focus on Medicare FFS beneficiaries, our measure selection emphasized prevention and management of chronic diseases that have high impact on these beneficiaries such as heart disease, diabetes mellitus, and chronic obstructive pulmonary disease. We believed that the quality measures used in the Shared Savings Program should be tested, evidence-based, target conditions of high cost and high prevalence in the Medicare FFS population, reflect priorities of the National Quality Strategy, address the continuum of care to reflect the requirement that ACOs accept accountability for their patient populations, and align with existing quality programs and value-based purchasing initiatives.

At this time, we continue to believe it is most appropriate to focus on quality measures that directly assess the overall quality of care furnished to FFS beneficiaries. The set of 33 measures that we adopted in the November 2011 Shared Savings Program final rule includes measures addressing patient experience, outcomes, and evidence-based care processes. Thus far, we have not included any specific measures addressing high cost services or utilization since we believe that the potential to earn shared savings offers an important and direct incentive for ACOs to address utilization issues in a way that is most appropriate for their organization, patient population, and local healthcare environment. We note

that while the quality performance standard is limited to these 33 measures, the performance of ACOs is measured on many more metrics and ACOs are informed of their performance in these areas. For example, an assessment of an ACO's utilization of certain resources is provided to the ACO via quarterly reports that contain information such as the utilization of emergency services or the utilization of CTs and MRIs.

As we have stated previously (76 FR 67872), our principal goal in selecting quality measures for ACOs was to identify measures of success in the delivery of high-quality health care at the individual and population levels. We believe endorsed measures have been tested, validated, and clinically accepted, and therefore, selected the 33 measures with a preference for NQF-endorsed measures. However, the statute does not limit us to using endorsed measures in the Shared Savings Program. As a result we also exercised our discretion to include certain measures that we believe to be high impact but that are not currently endorsed, for example, ACO#11, Percent of PCPs Who Successfully Qualify for an EHR Incentive Program Payment.

In selecting the final set of 33 measures, we sought to include both process and outcome measures, including patient experience of care (76 FR 67873). Because ACOs are charged with improving and coordinating care and delivering high quality care, but also need time to form, acquire infrastructure and develop clinical care processes, we continue to believe it is important to have a combination of both process and outcomes measures. We note, however, that as other CMS quality reporting programs, such as PQRS, move to more outcomes-based measures and fewer process measures over time, we may also revise the quality performance standard for the Shared Savings Program to incorporate more outcomes-based measures over time.

Therefore, we viewed the 33 measures adopted in the November 2011 Shared Savings Program final rule as a starting point for ACO quality measurement. As we stated in that rule (67 FR 67891), we plan to modify the measures in future reporting cycles to reflect changes in practice and improvements in quality of care and to continue aligning with other quality reporting programs and will add and/or retire measures as appropriate through the rulemaking process. In addition, we are working with the measures community to ensure that the specifications for the measures used under the Shared Savings Program are

up-to-date. We note that we must balance the timing of the release of specifications so they are as up-to-date as possible, while also giving ACOs sufficient time to review specifications. Our intention is to issue the specifications annually, prior to the start of the reporting period for which they will apply.

In the November 2011 Shared Savings Program final rule (76 FR 67873), we combined care coordination and patient safety into a single domain to better align with the National Quality Strategy and to emphasize the importance of ambulatory patient safety and care coordination. We also intended to continue exploring ways to best capture ACO care coordination metrics and noted that we would consider adding new care coordination measures for future years (67 FR 67877).

2. Changes to the Quality Measures Used in Establishing Quality Performance Standards That ACOs Must Meet To Be Eligible for Shared Savings

a. Background and Proposal

Since the November 2011 Shared Savings Program final rule, we have continued to review the quality measures used for the Shared Savings Program to ensure that they are up to date with current clinical practice and are aligned with the GPRO web interface reporting for PQRS. Based on these reviews, in the CY 2015 Physician Fee Schedule proposed rule, we proposed a number of measure additions, deletions and other revisions that we believed would be appropriate for the Shared Savings Program. An overview of changes we proposed is provided in Table 50 of the proposed rule (79 FR 40479 through 40481) which lists the measures that we proposed would be used to assess ACO quality under the Shared Savings Program starting in 2015. To summarize, we proposed to add 12 new measures and retire eight measures. We also proposed to rename the EHR measure in order to reflect the transition from an incentive payment to a payment adjustment under the EHR Incentive Program and to revise the component measures within the Diabetes and CAD composites. In total, we proposed to use 37 measures for establishing the quality performance standard that ACOs must meet to be eligible for shared savings. Although the total number of measures would increase from the current 33 measures to 37 measures under this proposal, we stated we did not anticipate that this would increase the reporting burden on ACOs because the increased number of measures is accounted for by measures

that would be calculated by CMS using administrative claims data or from a patient survey. The total number of measures that the ACO would need to directly report through the CMS Web site interface would actually decrease by one, in addition to removing redundancy in measures reported.

Finally, as part of the proposed changes, we proposed to replace the current five component diabetes composite measure with a new four component diabetes composite measure. In addition, we proposed to replace the current two component coronary artery disease composite measure with a new four component coronary artery disease composite measure. Under this proposal, 21 measures would be reported by ACOs through the GPRO web interface and scored as 15 measures.

Below, we summarize and group comments received on these proposals by first responding to general comments on our proposals and then by the method of data submission for the measure as listed in Table 50 of the proposed rule (79 FR 40479 through 40481) (that is, survey, claims, EHR incentive program, and the CMS web interface). In order to align the measures submitted through the CMS web interface with the PQRS and VM programs, we discuss specific comments in response to the proposed changes to the measures submitted through the CMS web interface with the comments received for these same measures for the PQRS and the VM programs. See Tables 79 and 80 in section III.K., for a discussion of and response to these comments.

General Comment: In addition to the comments that focus on individual measures, we received many general comments about the quality performance measures used in the Shared Savings Program. For example, we received many comments supporting the alignment between ACO, PQRS and VM quality measures and an increased focus on outcomes-based quality measures. Some commenters objected to the net increase in measures, believing there is underlying burden for providers even for claims-based measures. Additionally, many ACOs did not support the proposed new measures, suggesting, for example, they would be unnecessary because of the incentives inherent to the Shared Savings Program, or that, in general, the new proposed measures are inadequately defined, tested or benchmarked. These ACOs believed that many of the proposed new measures address clinical issues beyond an ACO's control and therefore should not be added. Other concerns about the

new measures were that they would require substantial change in clinical practice, would substantially add to the reporting burden, and/or are questionably related to improving care quality and/or patient outcomes.

Other commenters supported adding the new measures. One commenter, for example, stated that "the expanded measures are important utilization and management measures that our developing ACO would have likely considered and built into our ACO Cost, Utilization, and Risk dashboard anyway. From a clinical and system standpoint, these additions are key components of better managing avoidable utilization and costs. They are measures we would want to know regardless of the Proposed Rule." MedPAC suggested that CMS move quality measurement for ACOs, MA plans, and FFS Medicare in the direction of a small set of population-based outcome measures, such as potentially preventable inpatient hospital admissions, emergency department visits, and readmissions.

Response: We continue to believe it is appropriate to add, remove, and modify quality measures for the Shared Savings Program to reflect changes in clinical practice and for other program needs. We want to minimize any additional burdens this could create for ACOs and their ACO participants and ACO providers/suppliers. Therefore, we agree with the comments in support of the alignment between ACO, PQRS and VM for the quality measures submitted through the CMS web interface, and an increased focus on outcomes-based quality measures. We disagree with those ACOs that suggested certain proposed new measures would be unnecessary because of the incentives inherent to the Shared Savings Program. Instead, we agree with the commenter who noted that such measures can be important utilization and management tools that many ACOs may consider and build into their own internal monitoring systems as a way to help manage avoidable utilization and costs. Further, we believe certain proposed new measures highlight the value of discussions with patients about their care.

b. Survey Based Measure

- **CAHPS Stewardship of Patient Resources.** This measure is one of the unscored survey measures currently collected in addition to the seven scored survey measures that are already part of the current set of 33 measures under the Shared Savings Program. Information on the unscored survey measure modules is currently shared with the ACOs for informational purposes only. The

Stewardship of Patient Resources measure asks the patient whether the care team talked with the patient about prescription medicine costs. The measure exhibited high reliability during the first two administrations of the CAHPS survey, and during testing, the beneficiaries that participated in cognitive testing said that prescription drug costs were important to them. We proposed to add Stewardship of Patient Resources as a scored measure in the patient experience domain because we believe, based on testing, that this is an important factor for measuring a beneficiary's engagement and experience with healthcare providers. We also proposed that the measure would be phased into pay for performance as we plan to do for other new measures, using a similar process to the phase in that was used for the scored measure modules in the survey that are currently used to assess ACO quality performance.

Comment: Some commenters supported the proposed addition of this measure, agreeing that discussing the cost of medications is important to assess the possibility that medication costs may be a barrier to care or that the measure may be an indicator of a patient's satisfaction with the care he or she is receiving. Other commenters questioned how this discussion leads to a plan of action or a modified plan of treatment to improve care if the patient is unable to pay for the medication. These commenters asked us to further explain how we envision this measure improving patient care. Some believe it would be reasonable to include this measure under pay for reporting, but that additional discussions with the community would be needed in order to establish an appropriate benchmark for this measure, as this is a relatively new measure. Some thought that physician discussions with patients regarding medication cost would be appropriate for "high tier," costly medications, but would be of questionable value relative to measuring patient-centered, quality care delivery for more frequently prescribed, lower cost, generic medications and/or the extent to which patients take medications as prescribed. Some commenters suggested that it would be unnecessary and/or burdensome to add this measure. For example, commenters indicated that physicians do not and cannot know the co-pays for each drug under each insurance plan and product and that there would be tremendous patient dissatisfaction when inaccurate pricing or cost information is provided to the patient by the provider. Some

commenters believe this measure is unnecessary since encouraging adherence to medications is a key strategy for ACOs to reduce avoidable costs, and inability to afford medications is a key barrier to adherence, so ACOs already have an incentive to discuss the cost of medications with their patients.

Response: This measure asks patients whether any health care provider spoke to them about their prescription medication costs and does not require that physicians know the co-pays for each drug under each insurance plan and product. Additionally, discussing this topic with beneficiaries can lead a clinician to understand whether and how the beneficiary may struggle with payment for medications, a factor that can affect adherence to prescribed regimens. We can therefore envision a scenario where, once the issue is identified, a clinician participating in an ACO could inform and educate the beneficiary about less expensive options, such as the use of generic medications, or about available community resources, as part of the ACO's care coordination processes required under § 425.112(b)(4). This in turn could directly improve the quality of care the beneficiary receives by improving medication adherence and leading to greater beneficiary engagement. Because this measure is already part of the CAHPS survey, we do not believe it will increase reporting burden for the ACO. The CAHPS survey question is available in the CAHPS Survey for ACOs Quality Assurance Guidelines on the CAHPS for ACOs Web site. As discussed below, because this is a new measure, the measure will be pay-for-reporting for the first two reporting periods it is in use for all ACOs, regardless of the phase-in schedule to pay-for-performance, in order to provide time for the development of an appropriate benchmark.

Final Decision: We are finalizing our proposed addition of the CAHPS: Stewardship of Patient Resources measure. After the measure has been used in the program under pay for reporting for two reporting periods, it will be pay-for-reporting for the first performance year of an ACO's first agreement period and pay-for-performance for the ACO's second and third performance years. We continue to believe that it is important for physicians and others to discuss the beneficiary's perspective on the cost of medications because it is important to assess the possibility that medication costs may be a barrier to care. The measure exhibited high reliability

during the first two administrations of the CAHPS survey, and during testing, the beneficiaries that participated in cognitive testing said that prescription drug costs were important to them.

c. Claims Based Measures To Be Computed by CMS

- *Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM).* We proposed to add a 30-day all cause skilled nursing facility (SNF) readmission measure. CMS is the measure steward for this claims-based measure, which is under review at NQF under NQF #2510. This measure estimates the risk-standardized rate of all-cause, unplanned, hospital readmissions for patients who have been admitted to a SNF within 30 days of discharge from a prior inpatient admission to a hospital, CAH, or a psychiatric hospital. The measure is based on data for 12 months of SNF admissions. We believe this measure would help fill a gap in the current Shared Savings Program measure set and would provide a focus on an area where ACOs are targeting care redesign. ACOs and their ACO participants often include post-acute care (PAC) settings and the addition of this measure would enhance the participation of and alignment with these facilities. Even when the ACO does not include post-acute facilities formally as part of its organization, ACO providers/suppliers furnish other services that have the potential to affect PAC outcomes. Thus, this measure would emphasize the importance of coordinating the care of beneficiaries across these sites of care. Additionally, because this measure would be calculated from claims, there would not be a burden on ACOs to collect this information.

Comment: A number of commenters supported including the measure and/or the concept to align the incentives of ACOs and SNFs to lower their readmission rates. Some provided suggestions to further refine the measure, such as to use a risk-adjusted measure of potentially avoidable readmissions for SNFs. Although MedPAC recommended that CMS consider a risk-adjusted, potentially avoidable readmission measure for SNFs, they did support the addition of a SNF readmission measure because of the importance of post-acute care management and care transitions between settings in improving beneficiary care. Another commenter supported the measure but encouraged delay until such time as Medicare readmission policy links a portion of SNF payments to their readmission rates so that SNFs would bear risk/penalty

equal to that of other providers in order to incent readmissions reduction. Some commenters believe that it is unnecessary and duplicative to add this quality measure since it is an inherent part of the Shared Savings Program that an ACO will be penalized through a reduction in shared savings if it has a high rate of readmissions. They also argue that ACOs that use SNFs for higher-acuity patients could see an increase in SNF readmission rates and thus be inappropriately penalized. A commenter suggested ACO scores will be inappropriately affected when beneficiaries return to an ACO participant hospital after being discharged to a SNF that is not participating in the ACO. In such cases, an ACO may be unable to achieve the same level of collaboration needed to affect change as compared to ACOs that include one or more SNFs as ACO participants or ACO providers/suppliers. Concern was also expressed regarding the ability of ACOs to consistently monitor psychiatric hospital discharges since federal laws limit the use and disclosure of documentation regarding drug and substance abuse as well as mental health therapies. These commenters recommend removing psychiatric hospital admissions from this measure since ACOs currently do not receive mental health claims data and should not be held accountable for measures for which they are not able to collect and monitor data over the performance period. Operational concerns were also raised including data lags and that ACOs can only derive raw admissions/readmission rates from the monthly claims files and the commenters believe these rates are not useful for improving performance against benchmarks unless CMS provides the algorithm to apply the appropriate risk adjustment. These commenters indicate that ACOs face significant challenges in monitoring performance when reliable risk-adjusted rates of admissions and readmissions are not provided on a regular basis.

Response: We appreciate the numerous thoughtful comments. We disagree with commenters that this measure is unnecessary and duplicative because we continue to believe that including this measure would reinforce the importance of coordinating the care of beneficiaries across hospital and SNF sites of care. We have previously expressed our expectation that ACOs coordinate the care of beneficiaries across these sites regardless of whether there are any post-acute care (PAC) providers participating in the ACO (§ 425.112(b)(4)). Even when the ACO

does not include post-acute facilities formally as ACO participants or ACO providers/suppliers, ACO providers/suppliers furnish other services that have the potential to affect PAC outcomes. Thus, this measure would emphasize the importance of coordinating the care of beneficiaries across these sites of care. Additionally, because this measure is calculated from claims, there would not be a reporting burden on ACOs to collect this information. We appreciate the recommendations that we use a risk-adjusted, potentially avoidable SNF readmission measure, however, there is currently no such measure available for use. We note that the SNF 30-day all-cause readmission measure does exclude planned readmissions using a similar methodology to ACO-8 Risk-Standardized, All Condition Readmission. Unplanned readmission rates do provide ACOs with useful information to better coordinate care and work toward reducing the risk of readmissions for all patients, including patients coming from a SNF. Further, contrary to the assertion of some commenters, we note that the HIPAA Privacy Rule generally provides the same protections for mental health information as it does for all protected health information (with the exception of psychotherapy notes). See the Department's guidance on the HIPAA Privacy Rule and sharing information related to mental health, available at <http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/mhguidance.html>. Thus, ACOs that request claims data under § 425.704 for purposes of their own health care operations or the health care operations of their covered entity ACO participants and ACO providers/suppliers, in accordance with HIPAA requirements, already receive information about mental health therapies as part of those data sets.

Final Decision: We are finalizing our proposal to add this 30-day all-cause SNF readmission measure. After the measure has been used in the program under pay for reporting for two reporting periods, the measure will be pay-for-reporting in the first two performance years of an ACO's first agreement period and will transition to pay-for-performance in the final year of the ACO's agreement period. We believe this measure will help fill a gap in the current Shared Savings Program measure set and will provide a focus on an area where ACOs are targeting care redesign.

- *All-Cause Unplanned Admissions for Patients with Diabetes Mellitus (DM), Heart Failure (HF) and Multiple Chronic*

Conditions. We proposed to add three new measures to the Care Coordination/Patient Safety domain. The three new measures are for: All-cause unplanned Admissions for Patients with Diabetes Mellitus (DM), all-cause unplanned Admissions for Patients with Heart Failure (HF) and all-cause unplanned Admissions for Patients with Multiple Chronic Conditions (MCC). These three measures are under development through a CMS contract with Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (CORE) to develop quality measures specifically for ACO patients with heart failure, diabetes, and multiple chronic conditions. We believe that these measures are important to promote and assess ACO quality as it relates to chronic condition inpatient admission because these chronic conditions are major causes for unplanned admissions and the addition of these measures will support the ACOs' efforts to improve care coordination for these chronic conditions. These measures are claims-based, and therefore, we do not expect that they would impose any additional burden on ACOs.

The following is a summary of the comments we received regarding our proposal to add these three new claims-based measures for All-Cause Unplanned Admissions for Patients with DM, HF and MCC.

Comment: We received a wide variety of comments in response to the proposal to add these claims-based measures. Many commenters supported the use of claims-based outcome measures to reduce reporting burden for providers, however, concerns were raised regarding the lack of NQF endorsement. Some commenters supported adding one or more of these measures, agreeing that chronic condition inpatient admissions are major causes for unplanned admissions and that the addition of one or more of these measures would support the ACOs' efforts to improve care coordination. For example, a few commenters supported the addition of a measure for All Cause Unplanned Admission for Patients with Multiple Chronic Conditions as all efforts to manage chronic disease may help lead to better patient outcomes and control cost. Another commenter supported the measures but preferred collapsing them into one measure of potentially avoidable hospitalizations, because of concern that the proposed condition-specific measures will be statistically unreliable and subject to random variation that will limit their usefulness in distinguishing ACOs' actual performance. In addition, some

commenters urged CMS to ensure the measures are adjusted for planned readmissions, unrelated readmissions and socio-demographic status. Other commenters supported applying these measures in the Shared Savings Program as pay for reporting only at this time since these measures are still under development, accepted target rates are not available and the measures are not yet endorsed by NQF. Commenters requested additional definition of what "other multiple chronic conditions" would be measured. MedPAC supported an increase of outcome measures.

Finally, some commenters believe it is not possible to comment on measures that are still under development, and questioned the added benefit of including these measures since ACOs have an inherent incentive to avoid or reduce unplanned hospital admissions.

Response: We continue to believe that these measures are important to promote and assess ACO quality because these chronic conditions are major causes for unplanned admissions and the addition of these measures will support the ACOs' efforts to improve care coordination for beneficiaries with these chronic conditions. These measures are claims-based, and therefore, we do not expect that they would impose any additional reporting burden on ACOs. Many concerns were raised regarding the lack of NQF endorsement, but CMS intends on submitting all three measures to NQF for review in the future. Draft measure specifications were made available to the public during the measure development comment period during the spring and summer of 2014. CMS will provide final measure specifications to the public when available (typically in the early part of the performance year). The MCC measure cohort definition aligns with the NQF MCC Measurement Framework, which defines patients with MCCs as people "having two or more concurrent chronic conditions that . . . act together to significantly increase the complexity of management, and affect functional roles and health outcomes, compromise life expectancy, or hinder self-management."¹¹ The MCC measure cohort of chronic conditions includes conditions such as, but not limited to, Acute Myocardial Infarction, Stroke, and Chronic Obstructive Pulmonary Disease.

Final Decision: After considering the comments received in response to our

¹¹ National Quality Forum (NQF). Multiple Chronic Conditions Measurement Framework. 2012; <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdIdentifier=id&ItemID=71227>.

proposal to add these three measures, we will add the All-Cause Unplanned Admissions for Patients with MCC, HF, and DM measures as pay-for-reporting for two performance years. After this time, the measure will be pay-for-reporting for the first two performance years for new ACOs in their first agreement period before transitioning to pay for performance in performance year three. We believe that it is important to include these measures in the Shared Savings Program measure set since they were specifically developed for ACO populations and move the quality performance standard under the Shared Savings Program toward more outcome-based measures. DM, HF, and MCCs affect a large volume of Medicare beneficiaries and can result in high costs due to poorly coordinated care. As a result, these chronic conditions are a focus of many ACO care redesign activities. Finally, these measures are claims-based and therefore do not impose an additional burden on ACOs for data reporting.

d. Measure Submitted Through the EHR Incentive Program

• **Percent of PCPs who Successfully Meet Meaningful Use Requirements.**

Because downward adjustments to Medicare payments will begin in 2015 under the EHR Incentive Program, we proposed to modify the name and specifications for ACO #11 Percent of PCPs who Successfully Qualify for an EHR Incentive Program Payment so that it more accurately depicts successful use and adoption of EHR technology in the coming years. We note this measure would continue to be doubly weighted.

Comment: We received a range of comments regarding this proposal. Some agreed that it is necessary to rename the measure given that the EHR Incentive Program begins its transition to a payment adjustment effective in 2015. Some of the commenters, while agreeing with the proposed change, also provided additional specification suggestions such as to exclude certain physicians, such as hospitalists, from the denominator of this measure, stating that hospitalists are not PCPs when providing observation services. Another commenter requested that CMS clarify “the interaction of the Medicaid Meaningful Use program and the MSSP” and “the impact to non-PCP EPs”. Another commenter requested that CMS make the list of EPs available to ACOs intermittently throughout the performance year to aid ACOs in ensuring that all EPs attest in a timely manner. A commenter questioned why this measure in its current form is limited only to PCPs, as opposed to all

EPs that are ACO providers/suppliers. Others were concerned that there appeared to be no opportunity to exclude physicians such as those who retired, died, moved out the country, from the denominator of this measure. Finally, there were a number of commenters that suggested the measure should be dropped and not renamed, since it is a process measure and the commenters believe that this measure has no direct relationship to the quality of patient care.

Response: We continue to believe, as do a number of commenters, that this is an important measure that should be retained and renamed given that downward adjustments to Medicare payments will begin in 2015 under the EHR Incentive Program. We appreciate the suggestions from commenters that agree with the proposed change and provided additional specification suggestions. We are not persuaded by commenters that suggest this measure should be removed from the quality performance standard for the Shared Savings Program. On the contrary, we believe the measure directly supports the adoption and meaningful use of certified EHR technology, which is an important tool to support change in the health care delivery system including the steps being taken by ACOs to improve the quality and efficiency of care. The measure specifications will continue to align with the EHR Incentive Program definitions of hospital-based providers and will exclude observation services, accordingly. The measure specifications include Medicare and Medicaid eligible PCPs. Practitioners other than PCPs are not included in the measure at this time in efforts to focus on the meaningful use of certified EHRs in the provision of primary care services. This measure aligns with other HHS initiatives that support the adoption and meaningful use of certified EHR technology. For example, the HHS Office of the National Coordinator for Health Information Technology and CMS are managing \$27 billion in funding from the American Recovery and Reinvestment Act of 2009 and other sources to promote the adoption of electronic health records (EHR) in hospitals and doctor's offices.¹² More than 75 percent of eligible health care professionals, and over 90 percent of eligible hospitals, have already qualified for EHR incentive payments for using certified EHR technology. Retaining this measure in the quality performance standard for the Shared Savings Program will help

provide an additional and appropriate incentive to reinforce the adoption and meaningful use of certified EHR technology. Finally, performance on this measure is determined using EHR Incentive Program data and due to the EHR Incentive Program timelines and data collection, CMS will not be able to provide lists of EPs to ACOs throughout the performance year.

Final Decision: After consideration of the comments received, we are finalizing the proposal to modify the name and specifications of ACO-11 to the Percent of PCPs who successfully meet MU requirements.

e. Measures Submitted Through the CMS Web Interface

To align with PQRS, we proposed to add several measures submitted through the CMS web interface that we believed were appropriate for the ACO quality performance standard. The measures we proposed to add were:

• **Depression Remission at Twelve Months (NQF #0710).**

• **Diabetes Measures for Foot Exam and Eye Exam (NQF #0056 and #0055).**

• **Coronary Artery Disease (CAD): Symptom Management.**

• **Coronary Artery Disease (CAD): Beta Blocker Therapy—Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF<40%) (NQF #0070).**

• **Coronary Artery Disease (CAD): Antiplatelet Therapy (NQF #0067).**

• **Documentation of Current Medications in the Medical Record (NQF #0419).**

Additionally, we identified a number of the existing measures submitted through the CMS web interface that have not kept up with clinical best practice, are redundant with other measures that make up the quality performance standard, or that could be replaced by similar measures that are more appropriate for ACO quality reporting. For the reasons specified in the proposed rule, we proposed to no longer collect data on the following measures, and these measures would no longer be used for establishing the quality performance standards that ACOs must meet to be eligible to share in savings:

• **ACO #12, Medication Reconciliation after Discharge from an Inpatient Facility.**

• **ACO #22, Diabetes Composite measure: Hemoglobin A1c control (<8 percent).**

• **ACO #23, Diabetes Composite: Low Density Lipoprotein (<100) (NQF #0729).**

• **ACO #24, Diabetes Composite: Blood Pressure (<140/90) (NQF #0729).**

¹² <http://www.hhs.gov/news/press/2014pres/09/20140916a.html>.

- ACO #25, *Diabetes Composite: Tobacco Non-use* (NQF #0729).
- ACO #29, *Ischemic Vascular Disease: Complete Lipid Profile and LDL Control (<100 mg/dl)* (NQF #0075).
- ACO #30, *Ischemic Vascular Disease: Use of Aspirin or another Antithrombotic* (NQF #0068).

- ACO #32, *Coronary Artery Disease (CAD) Composite: Drug Therapy for Lowering LDL Cholesterol* (NQF #74).

Finally, given these proposed changes, we also proposed updates and revisions to the Diabetes and CAD Composite measures. We proposed that the Diabetes Composite include the following measures:

- ACO #26: Diabetes Mellitus: Daily Aspirin or Antiplatelet Medication Use for Patients with Diabetes Mellitus and Ischemic Vascular Disease.
- ACO #27: Diabetes: Hemoglobin A1c Poor Control.
- ACO #41: Diabetes: Foot Exam.
- ACO #42: Diabetes: Eye Exam.

We further proposed that the CAD Composite include the following measures:

- ACO #33: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy—Diabetes or Left Ventricular Systolic Dysfunction (LVEF<40%).
- ACO #43: Antiplatelet Therapy.
- ACO #44: Symptom Management.
- ACO #45: Beta-Blocker Therapy—Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF<40%).

We solicited comment on these composite measures and whether there are any concerns regarding the calculation of a composite score. Given the general concerns around composite measures and their use, we also solicited comment on how we combine and incorporate component measure scoring for the composite.

Comment: Most commenters supported the proposed removal and replacement of measures that may not align with current clinical guidelines or that appear to overlap with other measures currently in the measure set. At least one commenter specifically opposed removal of ACO #30, *Ischemic Vascular Disease: Use of Aspirin or another Antithrombotic* (NQF #0068) and the LDL measures, stating that there is disagreement on guidelines among professional organizations. Others expressed concern about the number of proposed changes that will require ACOs, in turn, to make changes to their internal processes and their EHRs to facilitate data collection. Some commenters raised general clinical or other methodological concerns about individual proposed measures

submitted through the CMS web interface. Our detailed responses to those comments can be found in Table 79 of section III.K. of this final rule with comment period.

We do, however, wish to note some specific comments relevant to our final policy decisions with respect to the quality performance measures used in the Shared Savings Program: (1) Commenters noted that the Patient Health Questionnaire 9 (PHQ-9) is specified for use in the Depression Remission measure (proposed ACO # 40), and that this tool is only one of several options available to practitioners. These commenters suggested not adding this measure until ACOs have had the opportunity to uniformly phase in the use of the PHQ-9 in order to meet the measure specification requirements. Additionally, commenters suggested that their ability to perform well on this measure may be limited if they cannot access the PHQ-9 score data from mental health care providers. (2) Many commenters did not support the proposed addition of the CAD: Symptom Management measure (proposed ACO # 44), stating they believe the measure lack primary care focus and that there are potential challenges in data collection. CMS also received a comment supporting the proposed addition of the CAD: Antiplatelet Therapy measure (proposed ACO # 43), however, this commenter recommended that if added, the measure only be used for pay-for-reporting. (3) Some commenters did not support the retirement of the 4 Diabetes Composite measures and 1 CAD Composite measure proposed to be removed due to the resources already invested in reporting these 5 measures. (4) CMS received comments suggesting that the quality performance standard under the Shared Savings Program should focus on broader categories of measures (such as preventive health measures) that are generalizable across providers and care settings, rather than measures that target specific providers or care settings.

Response: We continue to believe that the quality performance measures used in the Shared Savings Program should reflect current clinical guidelines. We appreciate the commenters' agreement with our proposed changes to remove and replace measures that are not in adherence with current clinical guidelines. In response to comments, included in Table 79 in section III.K, we will retain ACO #30, *Ischemic Vascular Disease: Use of Aspirin or another Antithrombotic* (NQF #0068). We note that we erroneously made the assertion

that this measure conflicts with current clinical guidelines. Therefore, due to the clinical importance of the measure, the measurement gap it addresses, and its alignment with the Million Hearts Campaign and PQRS, we will retain this measure.

Given the concerns raised by commenters, included in Table 80 of section III.K, regarding our proposal to use PHQ-9 for the Depression Remission measure, we will not finalize our proposal that the measure would be phased-in to pay-for-performance during the second and third performance years of an ACO's first agreement period. We will, however, finalize our proposal to use the measure to assess ACO quality, but only as pay-for-reporting for all three performance years of an ACO's first agreement period. We believe this approach will provide flexibility for ACOs to continue to use tools other than the PHQ-9, while providing the opportunity for ACOs to begin adopting this tool without harming their ability to achieve full points on the measure. Additionally, as noted above, the HIPAA Privacy Rule generally provides the same protections for mental health information as it does for all protected health information (with the exception of psychotherapy notes). We therefore do not believe there would be any unusual impediments to accessing the information required for reporting of this particular measure.

After consideration of the comments received and in order to align with the final measures that will be used in the PQRS program, we will not finalize the CAD: Symptom Management (proposed ACO-44) and CAD: Antiplatelet Therapy (proposed ACO-43) measures for the Shared Savings Program. See section III.K, Table 79, for comment discussion and response.

We believe it is important to make changes in the measures used to assess ACO quality to address the statutory mandate in section 1899(b)(3)(A) of the Act which requires the Secretary to determine appropriate measures to assess the quality of care furnished by the ACO, reflect current clinical practice, promote high quality care, and alignment with PQRS and National Quality Strategy. We therefore disagree with commenters that internal operational challenges that arise from changes in the measure set outweigh the benefit of such changes.

After considering the comments received regarding the proposed new measures, we are finalizing our proposal to add the following new measures that will be submitted by the ACO through the CMS web interface:

- *Documentation of Current Medications in the Medical Record* (NQF #0419).

- *Depression Remission at Twelve Months* (NQF #0710).

- *Diabetes Measures for Eye Exam* (NQF #0055).

For the reasons stated in section III.K., we decline to finalize our proposals to add the following measures:

- Diabetes: Foot Exam (NQF #0056)
- CAD: Antiplatelet Therapy (NQF #0067)
- CAD: Symptom Management
- CAD: Beta-Blocker Therapy—Prior Myocardial Infarction or Left Ventricular Systolic Dysfunction (LVSD) (NQF #0070)

We are not finalizing our proposal to add the CAD: Antiplatelet Therapy (NQF #0067) measure and instead will keep the measure it was designed to replace, ACO #30, *Ischemic Vascular Disease: Use of Aspirin or another Antithrombotic* (NQF #0068) because we have determined that it does not conflict with clinical guidelines, remains clinically important, addresses a measurement gap, and aligns with the Million Hearts Campaign and PQRS. We believe that retention of this measure in lieu of the proposed Antiplatelet Therapy measure will additionally reduce burden on ACOs that would otherwise need to revise their data collection processes to accommodate this change.

Additionally, we are finalizing our proposal to remove certain measures from the ACO quality performance standard including the following:

- ACO #12, *Medication Reconciliation after Discharge from an Inpatient Facility*.
- ACO #22, *Diabetes Composite measure: Hemoglobin A1c control (<8 percent)*.
- ACO #23, *Diabetes Composite: Low Density Lipoprotein (<100)* (NQF #0729).
- ACO #24, *Diabetes Composite: Blood Pressure (<140/90)* (NQF #0729).
- ACO #25, *Diabetes Composite: Tobacco Non-use* (NQF #0729).
- ACO #29, *Ischemic Vascular Disease: Complete Lipid Profile and LDL Control (<100 mg/dl)* (NQF #0075).
- ACO #32, *Coronary Artery Disease (CAD) Composite: Drug Therapy for Lowering LDL Cholesterol* (NQF #74).

Finally, given these changes, we are revising the Diabetes Composite to include the following measures:

- ACO #27: Diabetes: Hemoglobin A1c Poor Control (NQF #0059).
- ACO #42: Diabetes: Eye Exam (NQF #0055).

Although not previously proposed, in order to align with PQRS and in

response to commenter concerns about using this measure outside the composite, we are removing ACO #26, Diabetes Mellitus: Daily Aspirin or Antiplatelet Medication Use for Patients with Diabetes Mellitus and Ischemic Vascular Disease. While we believe the measure may be valid apart from the composite, we are swayed by the concerns raised by commenters as discussed in Table 79 in section III.K. We believe removing ACO–26 is consistent with our proposals to align with the PQRS program and remove redundancy of measures within the Shared Savings Program measure set. In addition, we believe removing this measure will reduce reporting burden for ACOs and may also help to improve performance on the diabetes composite. We also note that the removal of this measure would additionally alleviate some redundancy with ACO #30 *Ischemic Vascular Disease: Use of Aspirin or another Antithrombotic* (NQF #0068) which we are retaining for the reasons discussed above.

The CAD Composite will be removed since there is only one CAD measure remaining.

We believe that the final measure set as adopted in this final rule is appropriate for purposes of the ACO quality performance standard and in order to align with changes being made to the PQRS for the reasons specified above and in Tables 79 and 80 in section III.K. Additionally, we believe that our final decision to remove certain measures will improve alignment with best practices and reduce reporting burden for ACOs.

f. Summary of Changes to the ACO Quality Measures

We are finalizing the ACO quality performance measures as follows. In total, we will use 33 measures to establish the quality performance standards that ACOs must meet to be eligible for shared savings. Although the number of measures in the measure set remains at 33, we are reducing the number of measures reported through the CMS web interface by 5 to reduce burden. In addition, as discussed in section III.K., we are also reducing the number of patients ACOs are required to report on for each measure. This change will also reduce the burden of quality reporting for ACOs. The new measures will be pay-for-reporting for the first two performance years for all ACOs. After this initial period, the measures will be phased in to pay-for-performance over the course of an ACO's first agreement period with the exception of Depression Remission at 12 Months which will stay

at pay-for-reporting for all three performance years.

Specifically, we are finalizing the following changes to the Shared Savings Program quality measure set (see Table 81 for a list of the final measures and for further details of phase in to pay-for-performance during the agreement period):

- Add the CAHPS: Stewardship of Patient Resources measure as pay-for-reporting in the first performance year of an ACO's first agreement period and pay-for-performance in the second and third performance years.
- Add SNF 30-Day All-Cause Readmission measure and All-Cause Unplanned Admissions measures for Patients with Multiple Clinical Conditions, Heart Failure, and Diabetes as pay-for-reporting for the first two years of an ACO's first agreement period before transitioning to pay-for-performance in performance year three.
- Add Depression Remission at 12 Months (NQF #0710) measure as pay-for-reporting for all three performance years of an ACO's first agreement period.
- Replace ACO–12 Medication Reconciliation (NQF #0097) with “Documentation of Current Medications in the Medical Record” (NQF #0419).
- Add Diabetes: Eye Exam (NQF #0055).
- Modify name and specifications of ACO–11 from Percent of PCPS who successfully Qualify for an EHR Incentive Program Payment to the Percent of PCPs who Successfully Meet MU Requirements.

In addition, we are finalizing the retirement of 6 of the 7 measures we proposed to delete because they do not align with updated clinical guidelines or are similar to existing measures (ACO–22, 23, 24, 25, 29, and 32). We are not finalizing our proposal to remove ACO–30 *Ischemic Vascular Disease: Use of Aspirin or Another Antithrombotic* and are removing ACO–26 *Diabetes Mellitus: Daily Aspirin or Antiplatelet Medication Use for Patients with Diabetes Mellitus and Ischemic Vascular Disease* due to comments received and for the reasons discussed above and in section III.K, Table 79.

We are also not finalizing the following proposed measures, but instead will continue to consider them for the future given the measurement gaps and high-cost, high-volume conditions these measures address for the quality performance standard as discussed in Table 79 in section III.K:

- Diabetes: Foot Exam (NQF #0056).
- CAD: Antiplatelet therapy (NQF #0067).
- CAD: Symptom management.

- CAD: Beta-blocker therapy—prior Myocardial Infarction (MI) or LVSD (NQF #0070).

As a result, we will no longer have a CAD composite in the measure set and will only have 1 CAD measure in the

Clinical Care in the At-Risk Population domain (ACO# 33: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy—Diabetes or Left Ventricular Systolic Dysfunction (LVEF<40%)).

An overview of the changes we are finalizing is provided in Table 81, which lists the measures that will be used to assess ACO quality under the Shared Savings Program starting with the 2015 performance year.

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TABLE 81: Measures for Use in Establishing Quality Performance Standards that ACOs Must Meet for Shared Savings

Domain	ACO Measure #	Measure Title	New Measure	NQF #/Measure Steward	Method of Data Submission	Pay for Performance Phase In		
						R – Reporting P – Performance		
						PY1	PY2	PY3
AIM: Better Care for Individuals								
Patient/Caregiver Experience	ACO - 1	CAHPS: Getting Timely Care, Appointments, and Information		NQF #0005, AHRQ	Survey	R	P	P
	ACO - 2	CAHPS: How Well Your Doctors Communicate		NQF #0005 AHRQ	Survey	R	P	P
	ACO - 3	CAHPS: Patients' Rating of Doctor		NQF #0005 AHRQ	Survey	R	P	P
	ACO - 4	CAHPS: Access to Specialists		NQF #N/A CMS/AHRQ	Survey	R	P	P
	ACO - 5	CAHPS: Health Promotion and Education		NQF #N/A CMS/AHRQ	Survey	R	P	P
	ACO - 6	CAHPS: Shared Decision Making		NQF #N/A CMS/AHRQ	Survey	R	P	P
	ACO - 7	CAHPS: Health Status/Functional Status		NQF #N/A CMS/AHRQ	Survey	R	R	R
	ACO - 34	CAHPS: Stewardship of Patient Resources	X	NQF #N/A CMS/AHRQ	Survey	R	P	P
Care Coordination/ Safety	ACO - 8	Risk-Standardized, All Condition Readmission		Adapted NQF #1789 CMS	Claims	R	R	P
	ACO - 35	Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM)	X	NQF #TBD CMS	Claims	R	R	P
	ACO - 36	All-Cause Unplanned Admissions for Patients with Diabetes	X	NQF#TBD CMS	Claims	R	R	P
	ACO -37	All-Cause Unplanned Admissions for Patients with Heart Failure	X	NQF#TBD CMS	Claims	R	R	P
	ACO -38	All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions	X	NQF#TBD CMS	Claims	R	R	P
	ACO - 9	Ambulatory Sensitive Conditions Admissions: Chronic Obstructive Pulmonary Disease or Asthma in Older Adults (AHRQ Prevention Quality Indicator (PQI) #5)		Adapted NQF #0275 AHRQ	Claims	R	P	P
	ACO - 10	Ambulatory Sensitive Conditions Admissions: Heart Failure (AHRQ Prevention Quality Indicator (PQI) #8)		Adapted NQF #0277 AHRQ	Claims	R	P	P
	ACO - 11	Percent of PCPs who Successfully Meet Meaningful Use Requirements		NQF #N/A CMS	EHR Incentive Program	R	P	P

Domain	ACO Measure #	Measure Title	New Measure	NQF #/Measure Steward	Method of Data Submission	Pay for Performance Phase In		
						R – Reporting P – Performance		
						PY1	PY2	PY3
					Reporting			
	ACO -39	Documentation of Current Medications in the Medical Record	X	NQF #0419 CMS	CMS Web Interface	R	P	P
	ACO - 13	Falls: Screening for Future Fall Risk		NQF #0101 NCQA	CMS Web Interface	R	P	P
AIM: Better Health for Populations								
Preventive Health	ACO - 14	Preventive Care and Screening: Influenza Immunization		NQF #0041 AMA-PCPI	CMS Web Interface	R	P	P
	ACO – 15	Pneumonia Vaccination Status for Older Adults		NQF #0043 NCQA	CMS Web Interface	R	P	P
	ACO – 16	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow Up		NQF #0421 CMS	CMS Web Interface	R	P	P
	ACO – 17	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention		NQF #0028 AMA-PCPI	CMS Web Interface	R	P	P
	ACO – 18	Preventive Care and Screening: Screening for Clinical Depression and Follow-up Plan		NQF #0418 CMS	CMS Web Interface	R	P	P
	ACO – 19	Colorectal Cancer Screening		NQF #0034 NCQA	CMS Web Interface	R	R	P
	ACO – 20	Breast Cancer Screening		NQF #NA NCQA	CMS Web Interface	R	R	P
	ACO - 21	Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented		CMS	CMS Web Interface	R	R	P
Clinical Care for At Risk Population - Depression	ACO – 40	Depression Remission at Twelve Months	X	NQF #0710 MNCM	CMS Web Interface	R	R	R
Clinical Care for At Risk Population - Diabetes		Diabetes Composite (All or Nothing Scoring):		CMS Composite				
	ACO -27	ACO - 27: Diabetes Mellitus: Hemoglobin A1c Poor Control		NQF #0059 NCQA (individual component)	CMS Web Interface	R	P	P
	ACO - 41	ACO - 41: Diabetes: Eye Exam	X	NQF #0055 NCQA (individual component)	CMS Web Interface	R	P	P
Clinical Care for At Risk Population - Hypertension	ACO - 28	Hypertension (HTN): Controlling High Blood Pressure		NQF #0018 NCQA	CMS Web Interface	R	P	P
Clinical Care for At Risk Population - Ischemic Vascular Disease	ACO-30	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic		NQF #0068 NCQA	CMS Web Interface	R	P	P
Clinical Care for At Risk Population - Heart Failure	ACO - 31	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)		NQF #0083 AMA-PCPI	CMS Web Interface	R	R	P

Domain	ACO Measure #	Measure Title	New Measure	NQF #/Measure Steward	Method of Data Submission	Pay for Performance Phase In		
						R – Reporting P – Performance		
						PY1	PY2	PY3
Clinical Care for At Risk Population – Coronary Artery Disease	ACO - 33	Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – for patients with CAD and Diabetes or Left Ventricular Systolic Dysfunction (LVEF<40%)		NQF # 0066 ACC	CMS Web Interface	R	R	P

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The current quality scoring methodology is explained in the

regulations at § 425.502 and in the preamble to the November 2011 final

rule (76 FR 67895 through 67900). As a result of the additions, deletions, and revisions to the quality measure set being made in this final rule, each of the four domains will include the following number of quality measures (See Table 82 for details.):

- Patient/Caregiver Experience of Care—8 measures

- Care Coordination/Patient Safety—10 measures
- Preventive Health—8 measures
- At Risk Population—6 measures (including 5 individual measures and a 2-component diabetes composite measure)

Table 82 provides a summary of the number of measures by domain and the

total points and domain weights that will be used for scoring purposes under these changes. Otherwise, the current methodology for calculating an ACO's overall quality performance score will continue to apply. Table 83 provides the measures that are retired/replaced.

TABLE 82: NUMBER OF MEASURES AND TOTAL POINTS FOR EACH DOMAIN WITHIN THE QUALITY PERFORMANCE STANDARD

Domain	Number of individual measures	Total measures for scoring purposes	Total possible points	Domain weight (percent)
Patient/Caregiver Experience	8	8 individual survey module measures	16	25
Care Coordination/Patient Safety.	10	10 measures. Note that the EHR measure is double-weighted (4 points).	22	25
Preventive Health	8	8 measures	16	25
At-Risk Population	7	5 individual measures, plus a 2-component diabetes composite measure, scored as one..	12	25
Total in all Domains	33	32	66	100

TABLE 83: SHARED SAVINGS PROGRAM MEASURES RETIRED/REPLACED

Notes	Domain	Measure title	NQF measure #/ measure steward	Method of data submission	Pay for Performance Phase In R = Reporting P=Performance		
					Perform- ance Year 1	Perform- ance Year 2	Perform- ance Year 3
ACO #12 Replaced.	Care Coordination/ Patient Safety.	Medication Rec- onciliation: Rec- onciliation After Discharge from an Inpatient Fa- cility.	NQF #97 AMA- PCPI/NCQA.	GPRO Web Inter- face.	R	P	P
ACO #22 Retired.	At Risk Popu- lation—Diabetes.	Diabetes Com- posite (All or Nothing Scoring): Hemoglobin A1c Control (<8 per- cent).	NQF #0729 MN Community Measurement.	GPRO Web Inter- face.	R	P	P
ACO #23 Retired.	At Risk Popu- lation—Diabetes.	Diabetes Com- posite (All or Nothing Scoring): Low Density Lipoprotein (<100).	NQF #0729 MN Community Measurement.	GPRO Web Inter- face.	R	P	P
ACO #24 Retired— Redun- dant Measure.	At Risk Popu- lation—Diabetes.	Diabetes Com- posite (All or Nothing Scoring): Blood Pressure <140/90.	NQF #0729 MN Community Measurement.	GPRO Web Inter- face.	R	P	P
ACO #25 Retired— Redun- dant measure.	At Risk Popu- lation—Diabetes.	Diabetes Com- posite (All or Nothing Scoring): Tobacco Non Use.	NQF #0729 MN Community Measurement.	GPRO Web Inter- face.	R	P	P
ACO # 26 Retired— redundant measure.	At Risk Popu- lation—Diabetes.	Diabetes Com- posite: Daily As- pirin or Antiplatelet Medi- cation Use for Patients with Di- abetes Mellitus and Ischemic Vascular Dis- ease.	GPRO Web Inter- face.	R	P	P

TABLE 83: SHARED SAVINGS PROGRAM MEASURES RETIRED/REPLACED—Continued

Notes	Domain	Measure title	NQF measure #/ measure steward	Method of data submission	Pay for Performance Phase In R = Reporting P=Performance		
					Perform- ance Year 1	Perform- ance Year 2	Perform- ance Year 3
ACO #29 Retired.	At Risk Popu- lation—Ischemic Vascular Dis- ease.	Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control <100 mg/ dl.	NQF #75 NCQA	GPRO Web Inter- face.	R	P	P
ACO #32 Retired.	At Risk Popu- lation—Coronary Artery Disease.	Coronary Artery Disease (CAD) Composite: All or Nothing Scoring: Drug Therapy for Lowering LDL- Cholesterol.	NQF #74 CMS (composite)/ AMA-PCPI (indi- vidual compo- nent).	GPRO Web Inter- face.	R	R	P

We believe that these modifications to the quality measure set for the Shared Savings Program will further enhance the quality of care patients receive from ACO participants and ACO providers/suppliers, better reflect clinical practice guidelines, streamline measures reporting, and enhance alignment with PQRS and the EHR Incentive Program.

g. Effective Date and Phase In of Quality Measures

Proposal: We proposed that these measures changes would become effective beginning with the 2015 reporting period, and the 2015 performance year (PY). We also proposed that all quality measures would be phased in for ACOs with 2015 start dates according to the phase-in schedule in Table 81. We proposed that ACOs with start dates before 2015 would be responsible only for complete and accurate reporting of the new measures for the 2015 performance year and then responsible for either reporting or performance on measures according to the phase in schedule.

Comment: Most commenters did not separately provide comments on this specific proposal regarding the effective date for measure changes but addressed the general issue as part of their comments on individual measures or related issues, especially with respect to the effective date for benchmarking purposes. However, a number of commenters disagreed with the proposal to move certain new measures to pay for performance after only one year of pay for reporting. They suggested that an additional year of pay for reporting would be needed in order to adequately and fairly set benchmarks for pay for performance, especially for measures that have not been previously tested in any large scale health system and may

be newly or not yet accredited by the National Quality Forum (NQF).

Response: We are finalizing our proposal that quality measures will become effective for the Shared Savings Program quality performance standard beginning in 2015 and the phase-in schedule indicated in Table 81. Additionally, we are convinced by commenters that believe that an additional year of pay for reporting is needed by CMS and ACOs to fully implement new measures. Therefore, each new measure will be pay-for-reporting for its first two reporting periods in use. This additional time will help to ensure that ACOs have adequate time to phase in their own care processes and infrastructure before they are held accountable for performance and that CMS has adequate data to set benchmarks for new measures before they transition to pay for performance according to the phase-in schedule in Table 81. In other words, the phase-in schedule indicated in Table 81 applies to a measure after it has been pay-for-reporting for the first two reporting periods it is in use. In this case, the new measures we are finalizing will be pay-for-reporting for the 2015 and 2016 reporting periods, which will take precedence over the phase-in schedule for ACOs that are currently participating in the Shared Savings Program. Using new measures as pay-for-reporting for the first two reporting periods they are in use will provide adequate time and data necessary to set the benchmarks for the 2017 reporting period when the measures will transition to pay for performance under the phase in schedule indicated in Table 81.

For example, assume a new measure is scheduled to phase in with reporting in PY1, reporting in PY2, and performance in PY3. Further assume

that an ACO with a 2014 start date will be in its second performance year (PY2) when the measure becomes effective. In this example, according to the performance year phase-in schedule, the ACO would be responsible for complete and accurate reporting of the new measure in PY2 and for performance on the measure in PY3. However, because the measure is new and will be pay-for-reporting for the 2015 and 2016 reporting periods, this overrides the phase-in schedule because we would not have benchmark information for this ACO's PY3. In this example, if the ACO renews its participation agreement for a new agreement period then the ACO would be responsible for performance on the measure in PY1 of its new agreement period, because the measure was scheduled to be pay-for-performance in PY3 of the previous agreement period. If we change the assumptions in the example to an ACO with a start date of 2015, under the phase-in schedule the ACO would be responsible for performance in PY3 which corresponds with the 2017 reporting period, the first year in which the measure is available to be used for pay-for-performance. In other words, each new measure is pay-for-reporting until it is possible to use it as pay-for-performance, and whether the ACO is subject to pay-for-performance at that time is determined by the phase-in schedule in Table 81.

We are also revising § 425.502(a)(4) to provide that the quality performance standard for a newly introduced measure is set at the level of complete and accurate reporting for the first two reporting periods for which reporting of the measure is required. For subsequent reporting periods, the quality performance standard for the measure

will be assessed according to the phase-in schedule for the measure.

h. Aligning with PQRS sampling methodology

Proposal: As noted in the November 2011 Shared Savings Program final rule (76 FR 67900), the Shared Savings Program uses the same sampling method used by PQRS GPRO. Specifically, the sample for the ACO GPRO must consist of at least 411 assigned beneficiaries per measure set/domain. If the pool of eligible, assigned beneficiaries is less than 411, the ACO must report on 100 percent, or all, of the assigned beneficiaries sampled. In the proposed rule, we stated that to the extent that PQRS modifies and finalizes changes in the reporting requirements for group practices reporting via the GPRO web interface, we proposed to make similar modifications to ACO reporting through the GPRO web interface. Specifically, as discussed in section III.K. of this final rule with comment period, we proposed to reduce the GPRO web interface minimum reporting requirements for PQRS reporting from 411 to 248 consecutively ranked and assigned patients for each measure or 100 percent of the sample for each measure if there are less than 248 patients in a given sample. We proposed that the reduced sample for each measure for reporting through the GPRO web interface would also apply to ACOs. We stated that we believe that a reduction in the number of sampled beneficiaries would reduce reporting burden for ACOs while maintaining high statistical validity and reliability in results.

Comment: We received relatively few comments on this proposal, but most of those that commented supported the proposal. A majority of commenters also supported the PQRS proposal to reduce the reported sample size for groups of 100 or more EPs, and agreed that this smaller sample size would reduce reporting burden (please refer to section III.K.). However, a few commenters were concerned that a sample size of 248 may not adequately or accurately represent the diversity of an ACO's providers and suppliers, especially for larger ACOs. These ACOs can include mixed models of employed and independent-affiliated provider practices. Therefore, these commenters support reducing the sample size requirement only for smaller ACOs, such as those ACOs with 5,000 to 10,000 assigned beneficiaries. Alternatively, these commenters request that ACOs be given the option to continue to report a larger sample size if they prefer. A commenter also asked that CMS publish results that support

the statistical validity and reliability of the proposed reduction of the sample from 411 to 248.

Response: Specific responses to comments on this proposal can be found in section III.K.4.a. of this final rule with comment period. We appreciate the comments from stakeholders that support the proposal to reduce the sample size and agree that this change will reduce reporting burden for ACOs. Moreover, commenters agreed that a reduction in the sample size to 248 would continue to be statistically valid and reliable. As discussed in section III.K.4.a, our internal assessments performed for PQRS confirm this conclusion. Additionally, we clarify that the GPRO web interface tool will continue to contain an oversample of 616 patients at it has previously, however, the number required for reporting is being reduced from 411 to 248. Because we have concluded that a sample of 248 is statistically valid and reliable, we disagree that the reduced sample size will not adequately represent the diversity of the ACO's providers and suppliers. Further, we do not have a mechanism that would allow us to deviate from the established methodology used by the GPRO web interface, and therefore cannot offer an option at this time for ACOs to choose to be assessed on more than 248 patients. As noted above, the tool oversamples up to 616 patients, and ACOs may choose, but are not required, to report on all 616. We oversample to allow ACOs to include beneficiaries for quality reporting to replace beneficiaries ACOs are unable to report on, due to exclusions, so they can complete the minimum required number of patients. However, in accordance with the methodology previously adopted under PQRS, the ACO would only be assessed based on reporting for 248 patients using the existing sampling methodology that otherwise has been previously established.

In order to align with the policy being finalized for PQRS, we are reducing the required number of consecutively ranked patients reported for each measure module through the CMS web interface from 411 to 248. Because ACOs report using the same web interface tool used by PQRS, this reduction in the required sample size for reporting will reduce burden, while ensuring statistical validity and reliability is maintained. It also ensures consistency and equal treatment for all groups reporting through the GPRO web interface.

3. Request for Comments for Future Quality Measures

In the proposed rule (79 FR 40483), we indicated that in addition to the changes to the current set of measures for the Shared Savings Program discussed above, we were interested in public comment on additional measures that we may consider in future rulemaking. We particularly welcomed comments regarding the following issues:

- **Gaps in measures and additional specific measures:** We solicited comments on specific measures or measure groups that may be considered in future rulemaking to fill in gaps that may exist for assessing ACO quality performance.

- **Caregiver experience of care:** We solicited comment on additional specific caregiver experience of care measures that might be considered in future rulemaking.

- **Alignment with Value-Based Payment Modifier (VM) measures:** We solicited comment on whether there are synergies that can be created by aligning the ACO quality measure set with the measures used under the VM. Although we did not propose any changes to align with the measures used under the VM, we did seek comment on whether the VM composites should be considered in the future as a replacement for the two ACO claims-based ambulatory sensitive conditions admissions (ASCA) measures.

- **Specific measures to assess care in the frail elderly population:** We welcomed comments with suggestions of new measures of the quality of care furnished to the frail elderly population that we may consider adopting in future rulemaking.

- **Utilization:** We welcomed comments on whether it is sufficient for utilization information to be included in the aggregate quarterly reports to ACOs or whether utilization measures should also be used to assess the ACO's quality performance as an added incentive to provide more efficient care. If commenters were interested in having utilization measures included in the quality performance standard, we welcomed specific comments on what utilization measures would be most appropriate for future consideration and suggestions for how to risk adjust these measures.

- **Health outcomes:** We welcomed suggestions as to whether and when it would be appropriate to include a self-reported health and functional status measure in the quality performance standard. We specifically welcomed comments on the appropriateness of

using a tool such the Health Outcomes Survey for health plans which assesses changes in the physical and mental health of individual beneficiaries over time. We also welcomed suggestions for alternatives to self-reported measures that may be considered in the future.

- *Measures for retirement:* We solicited input from commenters on any measures that should be considered for retirement in future rulemaking. We welcomed comments on whether to continue to require “topped out” measures be included as pay for reporting measures. In addition, we noted that we were proposing changes to the benchmarking methodology for topped out measures.

- *Additional public health measures:* In the proposed rule, we noted that we may propose to include an additional preventive health measure in the quality measure set under the Shared Savings Program in future rulemaking. Specifically, we indicated that we were considering adding “Preventive Care and Screening: Unhealthy Alcohol Use: Screening and Brief Counseling” (NQF #2152). This measure would reflect screening of Medicare beneficiaries covered under the existing Medicare benefit referred to as the “Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse” benefit. We welcomed comments on the potential addition of this measure and noted that we would consider any comments received in developing any future proposal with respect to this measure.

Comment: Commenters identified a wide variety of specific measure gap areas that we should address, such as COPD, care coordination, medication management and adherence, preventive care/adult immunizations, pain, malnutrition, wounds, bladder control, outcome measures and cost/efficiency/utilization related measures. Some commenters provided suggestions for specific measures that we should consider in future rulemaking while other commenters provided more general suggestions about the types of additional measures that we should consider. For example, some commenters suggested that quality measures should be primarily designed to protect beneficiaries from inappropriate reductions in services by ACOs. Other commenters noted that to improve care for beneficiaries, the measures should focus on areas where: (a) CMS believes Medicare beneficiaries are receiving poor care today; and (b) it is feasible for an ACO to make changes in care that would improve care in those areas using the limited resources available in the Shared Savings

Program. Others opposed utilization measures, believing these types of measures are not necessary within the Shared Savings Program because of the inherent incentive for ACOs participating in the program to reduce unnecessary services and achieve savings. A commenter supported adding public health measures “. . . to help overcome the difficulties inherent in procedure-based measures that capture limited volumes of experience in rural settings.” This commenter provided additional suggestions, such as that we exercise caution in interpreting results from self-reported measures, because of a tendency of rural respondents to understate the true burden of chronic illness and travel. Another commenter emphasized that measure development should not entirely focus on outcomes measures because process measures can also improve outcomes. Some measures without clear clinical evidence (that is, lacking NQF endorsement) should be avoided. Furthermore, survey measures should be minimal (and not heavily weighted) due to subjectivity, cost of collection, and risk of inaccurate representation based on response rate. This commenter also recommended that the number of measures required to be reported should be realistic and CMS should move toward the use of composites and outcome measures. Refining the measurement strategy in this way over time will allow for ACOs to mature in function, which takes a few years, and CMS should structure measure selection and performance measurement to reflect growth from fledgling ACO to a mature ACO. CMS should set up data reporting to be automated as much as possible. Finally, a commenter suggested that complementing the measurement strategy should be a forum for communication among ACO participants to share best practices and lessons learned. Comments regarding “topped out” measures for retirement are included in the discussion below regarding the adjustment of the benchmarks for “topped out” measures.

Response: We appreciate receiving the many thoughtful suggestions. We will consider these suggestions further as we develop any future proposals for additional measures for the Shared Savings Program, which we would implement through rulemaking.

4. Electronic Reporting of Quality Measure Data

We believe that certified EHR technology used in a meaningful way is one piece of a broader health information technology infrastructure needed to reform the health care system

and improve health care quality, efficiency, and patient safety. Through our programs such as the Medicare and Medicaid EHR Incentive Programs and the Stage 2 meaningful use (MU) requirements we seek to expand the meaningful use of certified EHR technology (CEHRT). Adoption of CEHRT by ACO participants and ACO providers/suppliers may help support efforts to achieve improvements in patient care and quality, including reductions in medical errors, increased access to and availability of records and data, improved clinical decision support, and the convenience of electronic prescribing. Additionally, we believe that the potential for the Shared Savings Program to achieve its goals could be further advanced by direct EHR-based quality data reporting by ACOs and their ACO participants and ACO providers/suppliers. This could help reinforce the use of CEHRT, reduce errors in quality measure submission, and achieve data submission efficiencies. We believe ACOs and their providers should be leaders in encouraging EHR adoption and should be using CEHRT to improve quality of care and patient safety and to reduce errors.

Furthermore, beginning in 2015, eligible professionals that do not successfully demonstrate meaningful use of CEHRT will be subject to a downward payment adjustment under Medicare that starts at – 1 percent and increases each year that an eligible professional does not demonstrate meaningful use, to a maximum of – 5 percent. A final rule establishing the requirements of Stage 2 of the Medicare EHR Incentive Program appeared in the September 4, 2012 **Federal Register** (Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2 Final Rule) (77 FR 53968). Included in this final rule are the meaningful use and other requirements that apply for the payment adjustments under Medicare for covered professional services provided by eligible professionals failing to demonstrate meaningful use of CEHRT, including the CQM reporting component of meaningful use. As previously discussed in section III.M.2, we are finalizing a proposal to revise the name and the specifications for the quality measure regarding EHR adoption to take the changing incentives into account. Specifically, we are changing the name of ACO #11 from “Percent of PCPs Who Successfully Qualify for an EHR Incentive Program Payment” to “Percent of PCPs Who Successfully Meet Meaningful Use Requirements” to

more accurately reflect what is being measured.

Additionally, under a group reporting option established for the Medicare EHR Incentive Program (77 FR 54076 through 54078), EPs participating in an ACO under the Shared Savings Program who extract the data necessary for the ACO to satisfy the quality reporting requirements of the Shared Savings Program from CEHRT would satisfy the CQM reporting component of meaningful use as a group for the Medicare EHR Incentive Program. In addition to submitting CQMs as part of an ACO, EPs have to individually satisfy the other objectives and associated measures for their respective stage of meaningful use.

However, we clarified that if an EP intends to use this group reporting option to meet the CQM reporting component of meaningful use, then the EP would have to extract all of its CQM data from a CEHRT and report it to the ACO (in a form and manner specified by the ACO) in order for the EP to potentially qualify for the Medicare EHR Incentive Program. The ACO must also report the GPRO web interface measures and satisfy the reporting requirements under the Shared Savings Program in order to its EPs to satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program.

Although these group reporting requirements were established under the Medicare EHR Incentive Program, the Shared Savings Program regulations were not amended to reflect these reporting requirements. Therefore, we proposed to amend the regulations governing the Shared Savings Program to align with the requirements previously adopted under the Medicare EHR Incentive Program in order to provide that EPs participating in an ACO under the Shared Savings Program can satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program when the ACO reports GPRO web interface measures by adding new paragraph (d) to § 425.506. We proposed that this new paragraph would provide that EPs participating in an ACO under the Shared Savings Program satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program when: (1) The eligible professional extracts data necessary for the ACO to satisfy its quality reporting requirements from CEHRT; and (2) the ACO satisfactorily reports the ACO GPRO measures through a CMS web interface.

Although we did not propose any new requirements regarding EHR based

reporting under the Shared Savings Program, we welcomed suggestions and comments about issues which we would consider in developing any future proposals. We especially solicited comment on the feasibility of an ACO to be a convener and submitter of quality measures through an EHR or alternative method of electronically reporting quality measures to us. We indicated our interest in the opportunities and barriers to ACO EHR quality measure reporting, as well as ways to overcome any barriers. We also welcomed suggestions on alternative ways that we might implement EHR-based reporting of quality measures in the Shared Savings Program, such as directly from EHRs or via data submission vendors. We solicited comment on whether EHR reporting should be a requirement for all Shared Savings Program ACOs or if the requirement for EHR reporting should be phased in gradually, for instance through a separate risk track or by the establishment of a “core and menu” quality measure set approach in which we would establish a core set of required quality measures and then supplement these required measures with a menu of additional measures (such as EHR-based reporting) from which an ACO could choose. This approach could provide ACOs with additional flexibility and allow them to report on quality measures that better reflect any special services they provide. As an alternative, we also solicited comment on whether ACO providers/suppliers could use a local registry-like version of the GPRO web interface to capture relevant clinical information and to monitor performance on all Medicare patients throughout the year and to more easily report quality data to CMS annually.

Comment: We received a wide variety of suggestions from ACOs and other stakeholders. Most ACOs support CMS's decision not to propose any new requirements at this time regarding EHR based reporting, and they agree with aligning the Shared Savings Program with the EHR Incentive Program whereby EPs participating in an ACO can satisfy the CQM reporting component of meaningful use when the EP extracts data necessary for the ACO to satisfy its quality reporting requirements using a CEHRT and the ACO satisfactorily reports the GPRO measures through the CMS web interface. Some commenters believe the technical and operational barriers outlined in the proposed rule were severely understated. Healthcare Information and Management Systems Society (HIMSS) considered requiring

EHR-based reporting of quality measures in the Shared Savings Program to be premature. Commenters raised concerns that the current lack of interoperability capabilities for ACOs that are formed by disparate organizations, often hospitals and physician groups coming together, but using differing EHR platforms that do not communicate electronic data sufficiently to centralize data for quality reporting would limit the ability of ACOs to successfully report quality through an EHR. They state it will take significant resources and time to ensure that interoperability is achieved. Rather than requiring EHR-based reporting, some commenters suggested that CMS should give providers the option to report through EHRs.

Response: We appreciate the comments recommending that we not establish any new requirements at this time regarding EHR based reporting under the Shared Savings Program. We also appreciate the comments supporting aligning the Shared Savings Program with the EHR Incentive Program whereby EP participating in an ACO can satisfy the CQM reporting component of meaningful use when the EP extracts data necessary for the ACO to satisfy its GPRO reporting requirement using a CEHRT and the ACO satisfactorily reports the GPRO measures through the CMS web interface.

We will continue to work toward electronic reporting of quality measures, keeping in mind the unique relationship ACOs have with their ACO participants and ACO providers/suppliers. We understand and appreciate the feedback from those stakeholders who raised important concerns about the readiness of ACOs and EHR systems to report quality electronically under the Shared Savings Program. We will use the information provided by commenters to work with ACOs and other stakeholders to develop possible ways to encourage EHR adoption taking into account input from ACOs on challenges for ACO electronic collection and submission of measures. In addition, we will consider the input we have received from stakeholders when deciding what additional requirements should be proposed in future rulemaking to encourage EHR adoption and use by ACOs and their ACO participants and ACO providers/suppliers.

After consideration of the comments received regarding this proposal, we are finalizing our proposal to codify in the Shared Savings Program rules for 2015 and beyond that an eligible professional that is an ACO provider/supplier can satisfy the CQM reporting component of

meaningful use when the eligible professional extracts data from CEHRT necessary for the ACO to satisfy its quality reporting requirements under the Shared Savings Program and the ACO reports the GPRO measures through the CMS web interface. This policy will be codified at § 425.506(d) of the Shared Savings Program regulations. We emphasize that if an EP intends to use this group reporting option to meet the CQM reporting component of meaningful use, then the EP would have to extract all its CQM data from a CEHRT and report it to the ACO (in a form and manner specified by the ACO) in order for the EP to potentially qualify for the Medicare EHR Incentive Program. The ACO must also report the GPRO measures through the CMS web interface in order for its EPs to satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program.

Although this amendment to the regulations will align the Medicare Shared Savings Program regulations with the existing requirements under the Medicare EHR Incentive Program, we intend to take steps in the future to better align and integrate EHR use into quality reporting under the Shared Savings Program.

5. Quality Performance Benchmarks

a. Overview of Current Requirements

Section 1899(b)(3)(C) of the Act directs the Secretary to “establish quality performance standards to assess the quality of care furnished by ACOs” and to “seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care.” Under the current Shared Savings Program regulations at § 425.502, the following requirements with regard to establishing a quality performance benchmark for measures apply: (1) During the first performance year of an ACO’s agreement period, the quality performance standard is set at the level of complete and accurate reporting; (2) during subsequent performance years, the quality performance standard will be phased in such that ACOs will be assessed on their performance on certain measures (see Table 1 of the November 2011 Shared Savings Program final rule (76 FR 67889 through 67890), for details of the transition for each of the 33 measures); (3) we designate a quality performance benchmark and minimum attainment level for each measure, and establish a point scale for the level of achievement on each measure; and (4) we define quality

performance benchmarks using FFS Medicare data or using flat percentages when the 60th percentile is equal to or greater than 80.00 percent.

Section 425.502(b)(2) governs the data that CMS uses to establish the quality performance benchmarks for quality performance measures under the Shared Savings Program. Consistent with section 1899(b)(3)(C) of the Act, which requires CMS to seek to improve the quality of care furnished by ACOs participating in the Shared Savings Program over time, § 425.500(b)(3) states that in establishing the measures to assess the quality of care furnished by an ACO, CMS seeks to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both.

Subsequently, we discussed several issues related to the establishment of quality performance benchmarks in the CY 2014 PFS final rule with comment period (78 FR 74759 through 74764). In that rule (78 FR 74760), we finalized a proposal to combine all available Medicare FFS quality data, including data gathered under PQRS (through both the GPRO web interface tool and other quality reporting mechanisms) and other relevant FFS quality data reported to CMS (including data submitted by Shared Savings Program and Pioneer ACOs) to set the quality performance benchmarks for 2014 and subsequent reporting periods. In establishing this policy, we determined that it was appropriate to use all FFS data rather than only ACO data, at least in the early years of the program, to avoid the possibility of punishing high performers where performance is generally high among all ACOs. We did not finalize a proposal to use Medicare Advantage (MA) data alone or in combination with FFS data in the short-term. Instead, we stated in the CY 2014 PFS final rule with comment period (78 FR 74760) that we intended to revisit the policy of using MA data in future rulemaking when we have more experience setting benchmarks for ACOs.

Additionally, in the CY 2014 PFS final rule with comment period, we retained the ability to use flat percentages to set benchmarks when many reporters demonstrate high achievement on a measure, so that ACOs with high performance on a measure are not penalized (78 FR 74760). More specifically, we will now use all available FFS data to calculate benchmarks, including ACO data, except where performance at the 60th percentile is equal to or greater than 80 percent for individual measures. In these cases, a flat percentage will be used to set the benchmark for the

measure. This policy allows ACOs with high scores to earn maximum or near maximum quality points while still allowing room for improvement and rewarding that improvement in subsequent years.

As previously discussed, the first performance year of an ACO’s agreement period is pay for reporting only, so ACOs earn their maximum sharing rate for completely and accurately reporting all 33 quality measures. Quality performance benchmarks are released in subregulatory guidance prior to the start of the quality reporting period for which they apply so that as we phase in measures to pay for performance, ACOs are aware of the actual performance rates they will need to achieve to earn the maximum quality points under each domain. In the November 2011 Shared Savings Program final rule, we indicated our intent to gradually raise the minimum attainment level to continue to incentivize quality improvement over time and noted that we would do so through future rulemaking after providing sufficient advance notice with a comment period to allow for industry input (76 FR 67898). In the CY 2014 PFS final rule with comment period, we reiterated our policy of setting quality performance benchmarks prior to the reporting year for which they would apply (78 FR 74759). Specifically, we use data submitted in 2013 for the 2012 reporting period to set the quality performance benchmarks for the 2014 reporting period. However, we recognize that in the first few years of the Shared Savings Program, we will only have a limited amount of data for some measures, which may cause the benchmarks for these measures to fluctuate, possibly making it difficult for ACOs to improve upon their previous year’s performance. Stakeholders have also told us that they prefer to have a stable benchmark target so that they can be rewarded for quality improvement from one year to the next. Therefore, instead of modifying quality performance benchmarks annually, in the CY 2014 PFS final rule with comment period (78 FR 74761) we stated that we would set the benchmarks for the 2014 reporting year in advance using data submitted during 2013 for the 2012 reporting year, and continue to use that benchmark for 2 reporting years (specifically, the 2014 and 2015 reporting years). We further indicated our intention to revisit this issue in future rulemaking to allow for public comment on the appropriate number of years that a benchmark should apply before it is updated.

b. Revisions for Benchmarking Measures That Are “Topped Out”

In the discussion of measures in the CY 2015 Physician Fee Schedule proposed rule, we indicated that some measures may be topped out, meaning that all but a very few organizations achieve near perfect performance on the measure. Since publication of the quality performance benchmarks for the 2014 and 2015 quality reporting years, a number of ACOs have noted that using available national FFS data has resulted in some benchmarks where the 80th or 90th percentiles approach 100 percent performance on the measure. Stakeholders have suggested it is unreasonable to hold organizations, especially very large organizations such as ACOs to this high standard and that it may be easier for smaller and medium size physician practices to achieve higher levels of performance given their smaller patient populations. We believe these concerns have merit because we have looked at the FFS data submitted to CMS and agree it is possible that smaller practices or practices with smaller populations may be able to achieve these higher levels of performance more easily than larger practices or organizations with larger patient populations. Therefore, we proposed certain modifications to our benchmarking methodology to address the way that such “topped out” measures are treated for purposes of evaluating an ACO’s performance. Specifically, when the national FFS data results in the 90th percentile for a measure are greater than or equal to 95 percent, we would use flat percentages for the measure, similar to our policy under § 425.502(b)(2)(ii) of using flat percentages when the 60th percentile is greater than 80 percent to address clustered measures. We believe this approach would address concerns about how topped out measures affect the quality performance standard while continuing to reward high performance, and being readily understandable to all. We proposed to revise § 425.502(b)(2)(ii) to reflect this policy. We invited comments on this proposal. We also invited comments on other potential approaches for addressing topped out measures. We indicated that we would use any comments received to help develop any future proposals regarding topped out measures. For example, we welcomed comments on whether we should drop topped out measures from the measures set, fold them into composites, or retain them but make them pay for reporting only.

Comment: Commenters were generally in agreement with our

proposal to use flat percentages for topped out measures, which is consistent with our policy of using flat percentages when the 60th percentile is greater than 80 percent to address clustered measures. We received a wide variety of responses to our request for comment on what should be done with topped out measures through future rulemaking. Many commenters supported retaining such measures with the view that quality measures are intended to protect Medicare beneficiaries from receiving inappropriate care. If all but a few organizations achieve near perfect performance, the commenters believe it would be important to retain that measure to encourage better performance from the low performing organizations, and to prevent backsliding by the high performers. Other commenters, including MedPAC, suggested removing topped out measures to reduce reporting burden. Others suggested that topped out measures could be dropped or moved from being process-based to clinical outcome-based and be folded into composites to prevent “back sliding,” or that they could be considered “deemed met” without a reporting requirement but available for audit if so chosen.

Response: We appreciate the commenters’ support for the proposal to use flat percentages when the national FFS data results in the 90th percentile performing at greater than or equal to 95 percent. We also appreciate the additional suggestions regarding treatment of topped out measures and intend to consider this issue further in future rulemaking.

Final Decision: After consideration of the comments received on this issue, we are finalizing our proposal to use flat percentages when the national FFS data results in the 90th percentile for a measure are greater than or equal to 95 percent. We are also finalizing our proposed revisions to § 425.502(b)(2)(ii) to reflect this policy. Although this final policy is similar to our current policy for setting benchmarks based on flat percentages when the 60th percentile is equal to or greater than 80.00 percent, we clarify that this methodology would apply to all measures, including measures whose performance rates are calculated as ratios, for example, measures such as the ACO Ambulatory Sensitive Conditions Admissions and the All Condition Readmission measure. We believe it is appropriate to apply this methodology to all topped out measures, including measures whose performance rates are calculated as ratios. Measures calculated and reported as ratios may also become topped out

and we believe it is important to keep a consistent approach for addressing all Shared Savings Program measures that become topped out.

c. Quality Performance Standard for Measures That Apply to ACOs That Enter a Second or Subsequent Participation Agreement

As discussed previously, during an ACO’s first participation agreement period, the quality performance standard during the first performance year is initially set at the level of complete and accurate reporting, and then, during performance years 2 and 3 within the ACO’s first agreement period, the quality performance standard is phased in such that the ACO is assessed on its performance on selected measures. We did not directly indicate the quality performance standard that would apply if an ACO were to subsequently enter into a second or subsequent participation agreement. However, § 425.502(a)(1) provides that during the first performance year of an ACO’s agreement period, CMS will define the quality performance standard at the level of complete and accurate reporting of all quality measures. As drafted, this regulation could be read to imply that the quality performance standard for ACOs in the first performance year of a subsequent agreement period would also be set at the standard of full and accurate reporting. We do not believe it is appropriate for an ACO in a second or subsequent agreement period to report quality measures on a pay-for-reporting basis if they have previously reported these measures in a prior agreement period. The ACO would have gained experience reporting the quality measures during the earlier agreement period, and as a result, we do not believe it would be necessary to provide any further transition period. Rather, we believe it would be appropriate to assess the ACO’s actual performance on measures that have been designated as pay for performance during all 3 years of the second or subsequent participation agreement period.

Accordingly, we proposed to revise our regulations to expressly provide that during a second or subsequent participation agreement period, the ACO would continue to be assessed on its performance on each measure that has been designated as pay for performance. That is, the ACO would continue to be assessed on the quality performance standard that would otherwise apply to an ACO if it were in the third performance year of the first agreement period. We will do this by modifying § 425.502(a)(1) and (a)(2) to

indicate that the performance standard will be set at the level of complete and accurate reporting of all quality measures only for the first performance year of an ACO's first agreement period, and that during subsequent agreement periods, pay for performance will apply for all three performance years.

Comment: We received relatively few comments on this proposal. A number of those that responded supported the proposal. A few were hesitant to support it, suggesting that a performance standard for a quality measure should not be continued into a second or a subsequent participation agreement period if there have been any significant changes in the measure set and/or in the specifications used to calculate performance on the measures. In such cases, those measures that have changed should follow the same schedule as would apply to an ACO in its first agreement period. Another example of a concern these commenters raised is if an ACO with a 2013 start date (three year agreement for 2013 through 2015) chooses to sign a subsequent three year agreement (for 2016 through 2018), that requires it to accept risk, then the ACO would possibly be facing new benchmarks beginning in PY 2016 and would not be afforded a one year pay for reporting transition period to gain experience with the new benchmarks.

Response: We appreciate the comments in support of this proposal. We believe that concerns that were expressed by some commenters about changes in the measure set are addressed through the phase-in schedule for new measures, as outlined in Table 81, and our policy, finalized above, that all new measures will be pay-for-reporting for all ACOs for the first two reporting periods in which they are in use, regardless of the phase-in schedule. This will permit time for CMS to gather data for benchmarking and publish benchmarks prior to the start of the third reporting period in which a new measure is in use. This two year grace period will also permit ACOs to become accustomed to the measure before it becomes pay-for-performance. So in the example given by the commenter, the ACO with a 2013 start date would not be subject to pay-for-performance in its first year of the subsequent agreement period (starting in 2016) for any of the new measures finalized in this rule. The first opportunity for the new measures to be used as pay-for-performance would be for the 2017 reporting period, which would correspond to this ACO's second performance year of its subsequent agreement period. Because the ACO

would be in its subsequent agreement period, all measures would be pay-for-performance at that time, with the exception of measures that remain pay-for-reporting in all years, according to the phase-in schedule indicated in Table 81. For example, the Depression Remission at 12 Months measure (ACO# 40) is pay-for-reporting for all three years of an ACO's first agreement period. In a subsequent agreement period, ACOs will continue to be assessed on this measure as pay-for-reporting, which corresponds to the level of performance required in PY3 of the first agreement period.

Final Decision: We are finalizing our proposal to modify § 425.502(a) to indicate that for ACOs in a second or subsequent agreement period, all measures will be pay for performance for all three performance years unless the measure is designated as pay-for-reporting for all three years, as indicated in Table 81. We clarify that, as discussed in more detail above, this policy applies only to measures that have been in use for two years or more, for which benchmarks are available, and thus, would not apply to new measures, which are designated as pay-for-reporting during the first two reporting periods they are in use.

d. Timing for Updating Benchmarks

As discussed in the CY 2014 PFS final rule with comment (78 FR 74761), we have further considered suggestions from ACOs regarding the appropriate number of years that a benchmark should apply before it is updated. ACOs suggested that there be a longer period of time to gain experience with the performance measure, before the benchmark is further updated. ACOs also indicated that it would be desirable to set and leave benchmarks static for additional performance years so that they have a quality improvement target to strive for that does not change frequently. ACOs believe that a stable benchmark would enhance their ability to be rewarded for quality improvement, as well as quality achievement, from one year to the next. We recognize, however, that there could be some concerns about lengthening the period between updates to the quality performance benchmarks. The current benchmarks as discussed previously, for example, are based on a combination of all available Medicare FFS quality data, including data gathered under PQRS, the Shared Savings Program and Pioneer ACO Model, but not MA quality data. To the extent that the benchmarks are based on quality data reported by a large number of ACOs and other FFS entities, we believe it is reasonable to use them

to assess the quality performance of ACOs. Furthermore, as discussed in the 2014 PFS final rule with comment period (78 FR 74761), we are also persuaded that we should establish a longer period between updates to the benchmarks in order to provide ACOs with a more stable target for measuring quality improvement. In the absence of this stability, it could be very difficult to assess quality improvement from year to year.

In the 2014 PFS final rule with comment period, we noted that we intended to address the number of years between updates to the benchmarks again in future rulemaking in order to allow for public comment. Therefore, we considered how long benchmarks should be in place before they are updated. We considered a range of options, from setting benchmarks every 2 years to setting benchmarks every 5 years. For example, we considered the option of setting benchmarks every 3 years. However, we note that ACO agreement periods are 3 years long and a new cohort of ACOs enters the program each year. As a result, setting benchmarks every 3 years might advantage some ACOs over others, particularly ACOs that have an agreement period during which benchmarks are not updated. Therefore, we proposed to update benchmarks every 2 years. We believe 2 years is an appropriate amount of time because the Shared Savings Program is relatively new and we do not have extensive experience in setting benchmarks under the Shared Savings Program. Updating the benchmarks every 2 years would enable us to be more flexible and give us the ability to make adjustments more frequently if appropriate. We note, however, that we may revisit this policy as more ACOs enter the program, more FFS data is collected which could help us better understand to what extent benchmarks should vary from year to year, or if we make any future proposals regarding the use of MA quality data for setting benchmarks.

Accordingly, we proposed to revise § 425.502(b) to add a new paragraph (b)(4)(i), which would provide that CMS will update benchmarks every 2 years. To illustrate this proposed policy, the existing quality performance benchmarks, which are based on data submitted in 2013 for the 2012 reporting period would apply for a total of 2 performance years (the 2014 and 2015 performance years) after which we would reset the benchmarks for all ACOs based on data for the 2014 reporting period that is reported during 2015. These updated benchmarks would apply for the 2016 and 2017

performance years. This timeline is summarized in Table 85. Under this proposal, ACOs would have a stable target for quality achievement for 2 years, which should improve the opportunity for ACOs to be rewarded for improvement from year to year compared to that benchmark. We also proposed to revise § 425.502(b) to add a new paragraph (b)(4)(ii), which would provide that for measures introduced in the first year of the 2-year benchmarking cycle, the benchmark will be established in the second year and updated along with the other measures at the start of the next 2-year benchmarking cycle.

We solicited comment on this proposal. We specifically solicited comment on the appropriate number of years that a benchmark should remain stable before it is updated. We also welcomed comments about when annual updates might be appropriate such as when there is a substantive specification change to a measure between years. For instance, the age range used for the breast cancer screening measure is different in 2014 than in 2013, or when the measure owner modifies or retires a measure. Additionally, although we proposed to retain our current policy of using the most recent available data to set the quality performance benchmarks, we also solicited comment on whether data from other reporting periods should also be considered in establishing benchmarks that will apply for 2 performance years. Specifically, we sought input on whether data from multiple years should be used to help provide more stable benchmarks. For example, should data submitted for the 2013 and 2014 reporting periods be combined to set benchmarks for the 2016 and 2017 performance years?

Comment: We received a wide range of comments in response to this proposal. In general most commenters supported setting benchmarks for at

least two years but many, including some ACOs, supported a longer period of at least three years to align with the Shared Savings Program agreement period to provide more stability for ACOs. There were some commenters that suggested more frequent adjustment of benchmarks under certain situations, suggesting that more frequent benchmark updates may be necessary whenever there are substantive specification changes for a measure, such as changes in the dominator or frequency. For example, a commenter stated that even slight modifications to a measure specification could eliminate any opportunity to establish a valid benchmark and that CMS must therefore consider establishing new benchmarks when even “non-substantive” changes are made to measure. A commenter suggested that instead of the proposed two year interval, benchmarks should be adjusted annually if there is a statistically significant performance change across all organizations. Some commenters suggested the use of multiple years of data to set benchmarks, suggesting, for example, that some measures could be susceptible to year specific events that could skew results.

Response: We are finalizing our proposal to set benchmarks for two years to provide ACOs with stable quality improvement targets. We believe that setting benchmarks for two years provides ACOs with stable quality improvement targets while not advantaging some ACOs over others by setting them for three years. We also agree with commenters who suggested the use of multiple years of data to set benchmarks to reduce the effect that year to year variation might have on the benchmarks. Therefore, we will use up to 3 years of FFS data to set benchmarks, if available. This should provide sufficient stability to minimize

year to year variation while also representing reasonably current practices, if the data is available. The use of multiple years of FFS data to set benchmarks will apply to all newly established benchmarks, but will not affect existing benchmarks, which apply to the 2014 and 2015 performance years.

We are finalizing our proposal to set benchmarks for two years to provide ACOs with stable targets for quality improvement. In addition, we will use up to three years of FFS data to set benchmarks, if available. The use of multiple years of FFS data to set benchmarks will apply to all newly established benchmarks, but will not affect existing benchmarks, which apply to the 2014 and 2015 performance years. We are finalizing our proposal to revise § 425.502(b) to add a new paragraph (b)(4)(i) providing that CMS will update benchmarks every 2 years. In light of our decision to set the quality performance standard for a newly introduced measure at the level of complete and accurate reporting for the first two reporting periods for which the measure is in use, we are revising proposed § 425.502(b)(4)(ii) to provide that for newly introduced measures that transition to pay for performance in the second year of the 2-year benchmarking cycle, the benchmark will be established in that year and updated along with the other measures at the start of the next 2-year benchmarking cycle. For example, if a new measure is scheduled to become pay for performance in 2017 after being used for pay-for-reporting for 2015 and 2016, it will be set for the 2017 performance year and subsequently reset at the beginning of the next 2-year benchmarking cycle (2018–2019). In other words, such a measure would have its benchmark set for a single year before phasing into the biennial benchmarking schedule outlined in Table 84.

TABLE 84—TIMELINE FOR SETTING AND UPDATING QUALITY PERFORMANCE BENCHMARKS

Reporting period for data used to set benchmark	Year data is analyzed, and benchmark is published	Performance year and reporting period to which benchmark applies
2012	2013	2014 & 2015
2012, 2013, 2014	2015	2016 & 2017
2014, 2015, 2016	2017	2018 & 2019

6. Rewarding Quality Improvement

a. Current Approach to Rewarding ACOs for Both Quality Attainment and Quality Improvement

ACOs must meet a CMS-specified quality performance standard in order to

be eligible to share in savings. The Shared Savings Program quality performance standard currently consists of a set of quality measures spanning four domains that are collected via the patient and caregiver experience of care survey, calculated by CMS from internal

administrative and claims data, and submitted by the ACO through the CMS web interface. The four domains include patient/caregiver experience of care, care coordination/patient safety, preventive health, and at-risk populations. The measures collected

through the CMS web interface are also used to determine whether eligible professionals that bill through the TIN of an ACO participant qualify for the PQRS incentive payment or avoid the downward PQRS payment adjustment. Eligible professionals that bill through the TIN of an ACO participant may qualify for the PQRS incentive payment or avoid the downward PQRS payment adjustment when the ACO satisfactorily reports the ACO GPRO quality measures on their behalf.

Under current policy, the quality performance standard is defined at the level of full and complete reporting for the first performance year of an ACO's agreement period. After that, an ACO must meet certain thresholds of performance and is rewarded on a sliding scale in which higher levels of quality performance translate to higher rates of shared savings. This scale, therefore, rewards improvement over time, since higher performance translates to higher shared savings. For example, an ACO that performs at the 80th percentile one year and then at the 90th percentile the next year would receive a higher level of shared savings in its second year than its first year, based on its improved quality performance. In this way, ACOs are rewarded for both attainment and improvement. This is particularly true when benchmarks are stable for more than one year, as discussed earlier in this section.

We recognize that rewards for both quality attainment, as well as quality improvement are not always built in to pay-for-performance initiatives. For example, in HVBP (Hospital Value-Based Purchasing) hospitals are scored based on the higher of their achievement or improvement on specified quality measures, with some hospitals receiving incentive payments if their overall performance is high enough relative to their peers. In the November 2011 final rule establishing the Shared Savings Program (76 FR 67897), we indicated in response to comments that we believe the approach of offering more points for better quality performance also offers an implicit incentive for continuous quality improvements, since it incorporates a sliding scale in which higher levels of quality performance translate to higher sharing rates. We believed that high performing ACOs should do well under this approach since it recognizes and provides incentives for ACOs to maintain high quality performance in order to maximize their share of savings and minimize their share of losses.

b. Additional Rewards for Quality Improvement

ACOs and other stakeholders have suggested that the current quality points scale described above does not adequately reward ACOs for both quality attainment and improvement. They request that we further strengthen the incentives for quality improvement by including an additional explicit reward for those ACOs that improve from one year to the next.

As discussed previously, the existing quality performance standard includes a sliding point scale that rewards ACOs for certain levels of attainment. In addition, we note that under the final policy discussed above in which we will establish a stable quality performance benchmark for a period of 2 years, there should be an even greater opportunity for every ACO to demonstrate improvement and be rewarded for that improvement from year to year. However, we were persuaded by suggestions from stakeholders that an additional, more explicit reward should be included for ACOs that improve their quality scores from year to year. Therefore, we proposed to revise our existing quality scoring strategy to explicitly recognize and reward ACOs that make year-to-year improvements in their quality performance scores on individual measures.

To develop such an approach, we looked to the MA program, which has already successfully developed and implemented a formula for measuring quality improvement. The MA five star rating program computes an improvement change score which is defined as the score for a measure in a performance year minus the score in the previous performance year. The MA five star rating program then measures each plan's net quality improvement by calculating the total number of significantly improved quality measures and subtracting the total number of significantly declined quality measures. This is an approach that we believed was also appropriate for measuring quality improvement for ACOs. (For more details on the formula for calculating the MA quality improvement measure, see the discussion in "Medicare 2014 Part C & D Star Rating Technical Notes", Attachment I, page 80, which can be downloaded from the CMS Web site at <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html>.)

We continue to believe it is important to recognize that the Shared Savings

Program is not a managed care program. Unlike MA, this program's design retains FFS flexibility and the freedom of choice available to beneficiaries under Medicare Parts A and B which generally necessitates different program requirements. However, in this case we believe there would be significant advantages for the Shared Savings Program to adopt the formula for a quality improvement measure that MA has already developed and implemented rather than attempt to develop a new formula for a quality improvement measure. In particular, the MA measure formula has already been fully developed and vetted with stakeholders, in the context of the MA program, with detailed operational specifications and previously shared with the public.

In addition, we believe it is important to add a quality improvement measure to the Shared Savings Program in a manner that would minimize disruption for ACOs. We believe it would be undesirable for both ACOs and the program if the quality improvement measure were added in a way that required extensive revisions to the current quality measurement methodology, for example, reweighting of the four quality measure domains. Therefore, we proposed to add a quality improvement measure to award bonus points for quality improvement to each of the existing four quality measure domains. For each quality measure domain, we proposed to award an ACO up to two additional bonus points for quality performance improvement on the quality measures within the domain. These bonus points would be added to the total points that the ACO achieved within each of the four domains. Under this proposal, the total possible points that could be achieved in a domain, including up to 2 bonus points, could not exceed the current maximum total points achievable within the domain.

ACOs would achieve bonus points for this quality improvement measure in a domain if they achieve statistically significant levels of quality improvement for measures within the domain, as discussed below. Otherwise, the current methodology for calculating the ACO's overall quality performance score would continue to apply (see § 425.502(e) and 76 FR 67895 through 67900). Additional details about the proposal to incorporate bonus points into the quality performance scoring methodology are discussed in the CY 2015 Physician Fee Schedule proposed rule (79 FR 40490 through 40492). Highlights of the methodology we proposed are as follows:

The quality improvement measure scoring for a domain would be based on

the ACO's net improvement in quality for the other measures in the domain. The calculation of the quality improvement measure for each domain would generally be based on the formula used for the MA five star rating program, as follows:

Improvement Change Score = score for a measure in performance year minus score in previous performance year.

In general, for a measure to be eligible to be included for purposes of determining quality improvement and awarding bonus points in a domain for a performance year, the measure must be a measure for which an ACO was scored in both the performance year and the immediately preceding performance year. Measures that were not scored in both the performance year and the immediately preceding performance year, for example, new measures, would not be included in the assessment of improvement. Otherwise, for purposes of determining quality improvement and awarding bonus points, we would include all of the individual measures within the domain, including both pay-for-reporting measures and pay-for-performance measures. In determining improvement, the actual performance score achieved by the ACO on the measure would be used, not the score used to determine shared savings. In other words, we would calculate a performance score for each measure, regardless of whether it is pay for reporting or pay for performance, and include the score in the report we provide to the ACO. For example, all measures are pay for reporting in the first year of an ACO's first agreement period, but even though the ACO will receive full credit for all reported measures, its actual performance on those measures will also be scored and provided to the ACO for informational purposes. We believe it is appropriate to use these actual performance scores to assess improvement on a measure from year to year, regardless of whether the measure is designated as a pay for reporting or a pay for performance measure in that performance year because the performance scores achieved by the ACO provide the best indication of the actual change in quality performance by the ACO.

If the ACO is in its first performance year of its first agreement period, then it would not be possible, of course, to measure quality improvement. Therefore, for these ACOs the existing scoring methodology would continue to apply and no bonus points would be awarded. If an ACO in its second or subsequent performance year does not experience an improvement nor a

decline in quality performance for any of the selected measures compared to its previous reporting period, or it experiences an improvement for some measures but has an equal or greater number of measures where quality performance has declined, then the ACO would likewise not be awarded any bonus points. If an ACO renews a participation agreement, then the measurement of quality improvement would be based on a comparison between performance in the first year of the new agreement period and performance in the 3rd year of the previous agreement period.

For each qualifying measure, we would determine whether there was a significant improvement or decline between the two performance years by applying a common standard statistical test. (See the discussion of the t-test for calculating the MA quality improvement measure in "Medicare 2014 Part C & D Star Rating Technical Notes", Attachment I, page 80, which can be downloaded from the CMS Web site at <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html>). Statistical significance testing in this case assesses how unlikely it is that differences as big as those observed would be due to chance when the performance is actually the same. The test recognizes and appropriately adjusts measures at both high and low levels of performance for statistically significant levels of change. Under this methodology, we can be reasonably certain, at a 95 percent level of confidence, that statistically significant differences in an ACO's quality measure performance for a year compared to the previous year are real and not simply due to random variation in measure sampling.

The awarding of bonus points would be based on an ACO's net improvement within a domain, and would be calculated by determining the total number of significantly improved measures and subtracting the total number of significantly declined measures. Up to 2 bonus points would be awarded on a sliding scale based on the ACO's net improvement for the domain compared to the total number of individual measures in the domain.

Consistent with our current quality methodology, the total points earned for measures in each domain, including any quality improvement points, would be summed and divided by the total points available for that domain to produce an overall domain score of the percentage of points earned versus points available. The percentage score for each domain will be averaged together to generate a

final overall quality performance score and sharing rate for each ACO that will be used to determine the amount of shared savings or, if applicable the amount of losses it owes, consistent with the requirements under § 425.502(e).

In developing this proposal to award bonus points for quality improvement, we considered several alternative options. Specifically, we considered whether it would be more appropriate not to award bonus points but instead to include a computed quality improvement measure that would be incorporated into the current scoring methodology just as any other measure would be added. Under this alternative approach, we would increase the total possible points that could be awarded in a domain. However, we did not propose that approach because we believe that awarding bonus points would provide the desired incentive, would be more understandable and less disruptive, and would not require extensive changes to the quality performance standard. By awarding bonus points we also avoid the need to develop ways to avoid unfairly penalizing new ACOs. Similarly, ACOs that have already achieved a very high level of quality for an individual measure may not be able to achieve further statistically significant improvement for the measure. Such ACOs could otherwise be disadvantaged if they were not able to earn performance points for a new quality improvement measure added to the total measures in the domain. We believe our quality improvement proposal mitigates these concerns because the measure recognizes incremental improvement at higher levels of performance and does not impose any penalty on ACOs that have already achieved a high level of performance.

We also considered whether we should provide an even greater additional incentive by increasing the total possible bonus points, perhaps up to 4 points to provide a higher incentive for greater levels of quality improvement. However, we did not propose that option because we were concerned that awarding 4 points for the quality improvement measure could overweight the additional incentive for quality improvement given that the program already rewards higher performance with a greater share of any savings.

In addition, we had some concerns about whether it would be appropriate to use the "pay for reporting" data reported to us, given that this information does not affect an ACO's quality performance score in the first

performance year. Therefore, we considered whether the quality improvement score should apply only to those ACOs that have completed at least two performance years. Under this alternative approach, ACOs would have an opportunity to be assessed based on their actual quality measure performance before being assessed on their quality improvement scores. We did not select this approach because we wanted to provide an incentive that would apply as soon as possible in the agreement period. Furthermore, as noted earlier, we believe it would be appropriate to include pay-for-reporting measures for purposes of awarding bonus points since under § 425.500(f) ACOs are required to report pay-for-reporting measures completely, accurately, and timely.

We proposed to add a new paragraph (e)(4) to § 425.502 to incorporate this process for calculating bonus points for quality improvement into the quality performance scoring methodology. We solicited comments on this proposal and welcomed comments on the alternative approaches discussed in the proposed rule. We also solicited comments on whether there are other alternative approaches to explicitly rewarding quality improvement for ACOs, and whether the implicit reward for quality improvement provided under the current regulations is sufficient.

We also welcomed any suggestions on how the Shared Savings Program might integrate elements of other quality improvement methodologies such as those employed by HVBP or MA. Such comments would be considered in developing possible future proposals to further align with other Medicare quality improvement programs.

Comment: Commenters were supportive of explicitly recognizing and rewarding ACOs that make year to year improvements in the manner proposed. Many commenters, however, felt that our proposal did not go far enough and recommended instead that CMS award up to four bonus points (rather than two) for quality improvement in each of the existing four quality measure domains, or permit bonus points in one domain to influence the weighting of the domain. These commenters pointed out that the proposal to award up to two bonus points would increase the overall quality performance score for an ACO by at most 14 percent. Some commenters suggested additional approaches, such as awarding an additional 10 percent of shared savings for those ACOs that score in the top 10 percent on quality measures. Another example is a suggestion that ACOs be allowed to retain 50% of their share of

savings regardless of the MSR if their overall quality score improves year-over-year.

Response: We appreciate the overall support from commenters who generally agreed with the proposal to offer an additional and explicit reward for improving quality performance in the Shared Savings Program. This additional reward would complement and reinforce our current quality performance scoring system that implicitly takes into account improvements over prior performance and rewards ACOs with a greater share in savings for greater quality performance. We believe that adding an explicit incentive places even greater emphasis on quality improvement, encouraging all ACOs to continue to improve quality for their patient populations over time, in addition to maintaining existing high quality levels. The success of the Shared Savings Program is dependent in large part on ACOs further improving the quality of the care they provide, not merely maintaining current levels of quality. Further, we believe that the suggestions from some commenters to increase the additional quality improvement award to up to four bonus points have merit. Although we proposed the improvement measure to increase the domain score by up to 2 points, similar to other measures in the domain, we agree with commenters that increasing this to four bonus points would not appear to overweight the additional incentive since the additional bonus points can only increase a quality score by at most 25 percent overall. (That is, 4 bonus points per domain times 4 domains equals 16, which when divided by the 66 total points possible equals approximately 25 percent). Additionally, we have at least one measure (ACO #11, Percent of PCPs Who Successfully Qualify for an EHR Incentive Program Payment) that is doubly weighted at 4 points in order to emphasize the importance of adoption of EHR meaningful use. Permitting the quality improvement measure to be double weighted would similarly emphasize the importance of quality improvement, further encouraging ACOs to improve overall quality for their patient populations over time.

Final Decision: We are finalizing our proposal to provide an additional quality improvement reward for Shared Savings Program ACOs who demonstrate quality improvement on measures in a domain. We believe that this additional and explicit reward for quality improvement would complement and reinforce our current quality performance approach.

Specifically, for each quality measure domain, we will award an ACO up to four additional bonus points for quality performance improvement on the quality measures within the domain. These bonus points would be added to the total points that the ACO achieves within each of the four domains. The total possible points that can be achieved in a domain, including up to 4 bonus points, could not exceed the maximum total points achievable within the domain. For example, as shown in Table 82, the total possible points for the patient/caregiver experience domain, which has eight individual measures, is 16 total possible points. Under this new policy that we are finalizing to provide for quality improvement bonus points, the maximum possible points within this domain will remain 16. If an ACO scores 12 points and is awarded four additional bonus points for quality improvement then the ACO's total points for this domain would be 16. However, if instead this same ACO had scored 13 points, then this ACO's total points after adding the bonus points would still not exceed 16. Table 82, which shows the number of points available per domain under the revised quality performance standard, reflects the current quality measure scoring methodology which will continue. Consistent with our current quality scoring methodology, the total points earned for measures in each domain, including any quality improvement bonus points up to the total possible points for the domain, would be summed and divided by the total points available for that domain to produce an overall domain score of the percentage of points earned versus points available. The percentage score for each domain will be averaged together to generate a final overall quality performance score and sharing rate for each ACO that will be used to determine the percentage of savings it shares or, if applicable, the percentage of losses it owes, consistent with the methodology established under § 425.502(e).

The calculation of the quality improvement measure for each domain would generally be based on the formula used for the MA five star rating program, as follows:

Improvement Change Score = score for a measure in performance year minus score in previous performance year.

For each qualifying measure, we will determine whether there was a significant improvement or decline between the two performance years by applying a "t-test" which is a common standard statistical test, at a 95 percent

level of confidence. (See the discussion of the t-test for calculating the MA quality improvement measure in “Medicare 2014 Part C & D Star Rating Technical Notes”, Attachment I, page 80, which can be downloaded from the CMS Web site at <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html>). This test assesses how unlikely it is that differences as big as those observed would be due to chance when the performance is actually the same.

The bonus points, up to a maximum of 4 points, will be awarded in direct proportion to the ACO’s net improvement for the domain to the total number of individual measures in the domain. For example, there are eight individual measures for the patient/caregiver experience of care domain. If an ACO achieves a significant quality increase in all eight measures then the ACO would be awarded the maximum of four bonus points for this domain. However, if the ACO achieved a significant quality increase in only one of the eight measures in this domain and no significant quality decline on any of the measures then the ACO would be awarded bonus points for quality improvement in the domain that is $1/8$ times $4 = 0.50$. The total points that the ACO could achieve in this domain could still not exceed the current maximum of 16 points shown in Table 82. We are also finalizing our proposal to add a new paragraph (4) to § 425.502(e) to incorporate the new bonus points scoring methodology, but are revising the proposed language in order to reflect our decision to award up to 4 bonus points per domain.

7. Technical Corrections

Currently § 425.502(d)(2)(ii) states that ACOs must score above the minimum attainment level determined by CMS on 70 percent of the measures in each domain. If an ACO fails to achieve the minimum attainment level on at least 70 percent of the measures in a domain, CMS will take the actions described in § 425.216(c). We note that § 425.216, which addresses the actions we may take prior to termination of an ACO from the Shared Savings Program does not include a paragraph (c). To encompass all of the actions we may take prior to termination, we believe the correct reference should be to § 425.216 generally, and therefore, proposed to make a technical correction to § 425.502(d)(2)(ii) to eliminate the specific reference to paragraph (c) of § 425.216. We also proposed to correct a typographical error in this provision

by revising “actions describe” to read “actions described.”

In addition, we also proposed to make a technical correction to § 425.502(a)(2). This provision currently states that ACOs will be assessed on performance based on the minimum attainment level for certain measures. However, as explained above and in the November 2011 Shared Savings Program final rule (76 FR 67895 through 67896), ACO performance on a measure is assessed not only based on the minimum attainment level for the measure but also based upon the quality performance benchmark that has been established for that measure. This methodology for calculating the performance score for a measure is codified in the regulations at § 425.502(c). Accordingly, we proposed to amend § 425.502(a)(2) to state that ACO performance will be assessed based on the quality performance benchmark and minimum attainment level for certain measures.

We requested comments on these proposed technical corrections.

We received no objections to correcting the typographical errors and making these other minor technical corrections and are finalizing them as proposed.

N. Value-Based Payment Modifier and Physician Feedback Program

1. Overview

Section 1848(p) of the Act requires that we establish a value-based payment modifier (VM) and apply it to specific physicians and groups of physicians the Secretary determines appropriate starting January 1, 2015, and to all physicians and groups of physicians by January 1, 2017. On or after January 1, 2017, section 1848(p)(7) of the Act provides the Secretary discretion to apply the VM to eligible professionals as defined in section 1848(k)(3)(B) of the Act. Section 1848(p)(4)(C) of the Act requires the VM to be budget neutral. The VM program continues CMS’s initiative to increase the transparency of health care quality information and to assist providers and beneficiaries in improving medical decision-making and health care delivery.¹³

2. Governing Principles for VM Implementation

In the CY 2013 PFS final rule with comment period, we discussed the goals of the VM and also established that

specific principles should govern the implementation of the VM (77 FR 69307). We refer readers to that rule for a detailed discussion and list those principles here for reference.

- *A focus on measurement and alignment.* Measures for the VM should consistently reflect differences in performance among groups or solo practitioners, reflect the diversity of services furnished, and be consistent with the National and CMS Quality Strategies and other CMS quality initiatives, including the PQRS, the Shared Savings Program, and the Medicare EHR Incentive Program.

- *A focus on physician and eligible professional choice.* Physicians and other nonphysician eligible professionals should be able to choose the level (individual or group) at which their quality performance will be assessed, reflecting eligible professionals’ choice over their practice configurations. The choice of level should align with the requirements of other physician quality reporting programs.

- *A focus on shared accountability.* The VM can facilitate shared accountability by assessing performance at the group level and by focusing on the total costs of care, not just the costs of care furnished by an individual professional.

- *A focus on actionable information.* The Quality and Resource Use Reports (QRURs) should provide meaningful and actionable information to help groups and solo practitioners identify clinical, efficiency and effectiveness areas where they are doing well, as well as areas in which performance could be improved by providing groups and solo practitioners with QRURs on the quality and cost of care they furnish to their patients.

- *A focus on a gradual implementation.* The VM should focus initially on identifying high and low performing groups and solo practitioners. As we gain more experience with physician measurement tools and methodologies, we can broaden the scope of measures assessed, refine physician peer groups, create finer payment distinctions, and provide greater payment incentives for high performance.

3. Overview of Existing Policies for the Physician VM

In the CY 2013 PFS final rule with comment period (77 FR 69310), we finalized policies to phase-in the VM by applying it beginning January 1, 2015, to Medicare PFS payments to physicians in groups of 100 or more eligible professionals. A summary of the

¹³ Kate Goodrich, et al. “A History and a Vision for CMS Quality Measurement Programs”. Joint Comm’n J. Quality & Patient Safety. 2012. 38,465, available at <http://www.ingentaconnect.com/content/jcaho/jcqs/2012/00000038/00000010/art00006>.

existing policies that we finalized for the CY 2015 VM can be found in the CY 2014 PFS proposed rule (78 FR 43486 through 43488). Subsequently, in the CY 2014 PFS final rule with comment period (78 FR 74765 through 74787), we finalized policies to continue the phase-in of the VM by applying it starting January 1, 2016 to payments under the Medicare PFS for physicians in groups of 10 or more eligible professionals.

4. Provisions of This Final Rule With Comment Period

As a general summary, we proposed the following VM policies in the CY 2015 PFS proposed rule:

- To apply the VM to all physicians and nonphysician eligible professionals in groups with two or more eligible professionals and to solo practitioners starting in CY 2017.

- To make quality-tiering mandatory for groups and solo practitioners within Category 1 for the CY 2017 VM. Where solo practitioners and groups with two to nine eligible professionals would be subject only to any upward or neutral adjustment determined under the quality-tiering methodology.

- To tailor the application of the VM to physicians and nonphysician eligible professionals participating in the Medicare Shared Savings Program (Shared Savings Program), the Pioneer ACO Model, the CPC Initiative, or other similar Innovation Center models or CMS initiatives starting in CY 2017.

- To clarify the exclusion of non-assigned claims for non-participating providers from the VM.

- To increase the amount of payment at risk under the VM from 2.0 percent in CY 2016 to 4.0 percent in CY 2017.

- To align the quality measures and quality reporting mechanisms for the VM with those available to groups and individuals under the PQRS during the CY 2015 performance period.

- To expand the current informal inquiry process to allow additional corrections for the CY 2015 payment adjustment period.

- To address the concerns raised by NQF regarding the per capita cost measures in the cost composite.

In this final rule with comment period, we discuss the proposed policies, the comments received, our responses to the comments, and a brief statement of our final policy.

Comment: We received some comments on the VM in general that were not related to any specific proposal that we made in the proposed rule. Several commenters suggested that the CMS-hierarchical condition categories (HCC) Risk Adjustment methodology used in the total per capita cost

measures for the VM does not accurately capture the additional costs associated with treating the sickest beneficiaries. Some of these commenters stated that groups that work exclusively in post-acute and long-term care settings would be unable to perform well on cost measures under the current methodology. Commenters suggested that we should include the place of service where the beneficiary received care in our methodology to set cost benchmarks such that groups would be compared against other groups that treat beneficiaries who are also receiving care in that type of location.

Another commenter suggested that we add an additional adjustment for SNF CPT codes to account for higher costs of beneficiaries in this location. One commenter suggested that CMS exclude beneficiaries who receive a major organ transplant from our cost and quality measures because he believes that prospective HCC risk adjustment would not account for these added costs in the performance period. Another commenter stated that beneficiaries who receive care at home typically have high HCC scores and higher costs. This commenter suggested that CMS should consider exempting practices from the VM who treat a high number of beneficiaries with the highest HCC scores or those with more than a certain number of chronic conditions or activities of daily living dependencies, change the risk adjustment methodology to include the frailty adjuster used in the PACE program, or add “recognition of savings from expected costs.”

Response: We appreciate the concerns raised by commenters and agree that it is important to make adjustments for differences in beneficiary characteristics that impact health and cost outcomes and are outside of the control of the provider. We continue to believe that our current methodology of using HCC scores that include adjustments for Medicare and Medicaid eligibility status in addition to diagnoses, and truncating costs at the 99th percentile for the highest cost beneficiaries, help address these concerns. While, the VM program does not, in the aggregate, adjust costs using an institutional risk score, the Medicare Spending per Beneficiary measure that will be used as part of the cost composite in 2014 does adjust costs based on whether a beneficiary recently required long-term institutional care as well as for whether a beneficiary is new to the Medicare program. We addressed the idea of adjusting cost measures for differences in site of service, as it pertained to hospitals, in the FY 2012 IPPS Final Rule (76 FR 51825). We continue to believe that such

adjustments would undermine the ability of our measures to meaningfully capture differences in Medicare spending. To address concerns regarding specialties that might routinely treat more complex and consequently more costly beneficiaries, we finalized in the CY 2013 PFS final rule with comment period that we would apply a specialty adjustment to all cost measures used in the VM (78 FR 74776). This enables groups' costs to be compared to similarly-comprised groups, based on specialty. In 2011, an independent analysis concluded that this risk-adjustment methodology is effective at predicting actual costs, even for beneficiaries with serious or multiple chronic illnesses.¹⁴ Moreover, the academic literature notes the multi-variant nature of care quality and the importance of defining measures across rather than simply within care settings.¹⁵

We note that high costs within the post-acute and long-term care settings present a unique opportunity for these providers to improve performance on cost and quality measures. While we continue to encourage providers to report quality measures for patients in these settings and to use the information contained in their QRUR to improve and achieve high levels of performance, we will continue to monitor these groups and solo practitioners' performance under the VM and continue to explore potential risk adjustment refinements..

a. Group Size

As noted in section III.N.1, section 1848(p)(4)(B)(iii)(II) of the Act requires the Secretary to apply the VM to items and services furnished under the PFS beginning not later than January 1, 2017, for all physicians and groups of physicians. Therefore, we proposed to apply the VM in CY 2017 and each subsequent calendar year payment adjustment period to physicians in groups of physicians with two or more eligible professionals and to physicians who are solo practitioners (79 FR 40493–40495). For purposes of the VM, we defined a physician, a group of physicians, and an eligible professional in the CY 2013 PFS final rule with comment period (77 FR 69307–69310). We proposed to define a “solo practitioner” at § 414.1205 as a single Tax Identification Number (TIN) with one eligible professional who is identified by an individual National

¹⁴ Gregory C. Pope, et al. “Evaluation of the CMS–HCC Risk Adjustment Model: Final Report.” (March 2011).

¹⁵ Tracy E. Spinks, et al. Delivering high-quality cancer care: The critical role of quality measurement. *Healthcare*. 2014. 2,53–62.

Provider Identifier (NPI) billing under that TIN. We noted that this proposal to apply the VM to all solo practitioner physicians and all groups of physicians would complete our phase-in of the VM as required by the Act.

In the proposed rule, we stated our belief that we can validly and reliably apply the VM to groups with two or more eligible professionals and to solo practitioners (79 FR 40494). We noted that we conducted statistical reliability analysis on the PQRS quality measures and the VM cost measures reported in the 2010 and 2011 group and individual Quality and Resource Use Reports (QRURs) (78 FR 43500 through 43502) and found that 98 percent of the PQRS measures included in the analysis, which were substantially similar to the PQRS measures that will be assessed during performance period CY 2015 for purposes of the VM, were highly reliable. As stated in the proposed rule,

we believe that these results suggest that we can reliably apply these measures to solo practitioners and groups (79 FR 40494). In section III.N.4.h, we discuss the reliability of the all-cause readmission measure and the policy we are finalizing to address reliability concerns regarding that measure.

In Table 55 of the proposed rule, we presented the number of groups, eligible professionals, physicians, and nonphysician eligible professionals in groups of various sizes based on an analysis of CY 2012 claims with a 90-day run-out period (79 FR 40494). We estimated that our proposals to apply the VM to all groups with two or more eligible professionals and to all solo practitioners in CY 2017 would affect approximately 83,500 groups and 210,000 solo practitioners (as identified by their TINs). We further estimated that the groups consist of approximately 815,000 physicians and 315,000

nonphysician eligible professionals (79 FR 40493).

For this final rule with comment period, we have updated Table 55 from the proposed rule, using CY 2013 claims with a 90-day claim run-out period and including TINs that participated in the Shared Savings Program, the Pioneer ACO Model, or the Comprehensive Primary Care Initiative in 2013. Table 86 shows the number of groups, eligible professionals, physicians, and nonphysician eligible professionals in groups of various sizes. We note that the number of eligible professionals includes other practitioners, such as physician assistants and nurse practitioners, in addition to physicians. We estimate that final policy to apply the VM to all physicians in groups with two or more eligible professionals and to all physicians who are solo practitioners in CY 2017 would affect approximately 900,000 physicians.

TABLE 86—ELIGIBLE PROFESSIONAL/PHYSICIAN GROUP SIZE DISTRIBUTION (2013 CLAIMS)

Group size	Number of groups (TINs)*	Eligible professionals (EPs)	Number of physicians	Number of nonphysician EPs	Percent of physicians	Percent of nonphysician EPs
100+ EPs	1,345	404,738	297,175	107,563	33	30
50–99EPs	1,753	119,979	81,679	38,300	9	11
25–49 EPs	3,926	134,038	90,141	43,897	10	12
20–24 EPs	1,957	42,733	29,112	13,621	3	4
10–19 EPs	8,697	117,164	78,893	38,271	9	11
2–9 EPs	69,455	244,800	171,627	73,173	19	20
1 EP	205,084	205,084	159,770	45,314	18	13
Total	292,217	1,268,536	908,397	360,139	100	100

* The number of groups (TINs) include TINs that have one or more EPs participating in the Shared Savings Program, the Pioneer ACO Model, or the Comprehensive Primary Care Initiative.

In the proposed rule (79 FR 40494), we stated that in the CY 2014 PFS final rule with comment period, we finalized the proposal that if we are unable to attribute a sufficient number of beneficiaries to a group of physicians subject to the VM, and thus, are unable to calculate any of the cost measures with at least 20 cases, then the group's cost composite score would be classified as "average" under the quality-tiering methodology (78 FR 74780 through 74781). However, we noted this policy was codified in § 414.1270(b)(5) as a group of physicians subject to the value-based payment modifier will receive a cost composite score that is classified as "average" under § 414.1275(b)(2) if such group does not have at least one cost measure with at least 20 cases. We stated that we believe the regulation text at § 414.1270(b)(5) better reflects the intent of this policy, and accordingly, we proposed to clarify that the description of this policy in the preamble of the CY 2014 PFS final rule with comment period (78 FR 74780

through 74781) should be the same as the regulation text at § 414.1270(b)(5). We also proposed to apply the same policy to groups and solo practitioners beginning in CY 2017. That is, a group or solo practitioner would receive a cost composite score that is classified as "average" under the quality-tiering methodology if the group or solo practitioner does not have at least one cost measure with at least 20 cases. We proposed to revise § 414.1270 accordingly.

We proposed to revise § 414.1210 to reflect that beginning in the CY 2017 payment adjustment period, the VM would be applied to physician and nonphysician eligible professionals in groups with two or more eligible professionals and to solo practitioners based on the performance period described at § 414.1215 (79 FR 40495). Accordingly, we proposed to amend the regulations under subpart N to add references to solo practitioners. We solicited comments on all of these proposals.

The following is summary of the comments we received on these proposals.

Comment: We received one comment that supported our proposed definition of a "solo practitioner."

Response: We appreciate this comment and are finalizing the definition of a "solo practitioner" to mean, "a single Taxpayer Identification Number (TIN) with one eligible professional who is identified by an individual National Provider Identifier (NPI) billing under the TIN." We are codifying this definition at § 414.1205.

Comment: Several commenters expressed concern that the cost measures potentially have little relevance to some provider groups and may leave some with an arbitrary label of "average" cost, if the minimum case number requirement for the cost measure is not met due to an insufficient number of beneficiaries being attributed to the group.

Response: As we stated in the CY 2014 PFS final rule with comment

period (78 FR 74780), we continue to believe that groups that are attributed fewer than the minimum case size of 20 beneficiaries would not allow for the calculation of reliable cost measures. We are concerned that not classifying the group as “average” when it has fewer than 20 attributed beneficiaries for at least one cost measure would increase the likelihood that its cost measures could fluctuate greatly from year to year. Therefore, we are finalizing our proposal that beginning in CY 2017 a group or solo practitioner will receive a cost composite score that is classified as “average” under the quality-tiering methodology if the group or solo practitioner does not have at least one cost measure with at least 20 cases and codifying the policy as proposed in § 414.1270. We are also finalizing our proposal to clarify that the description of this policy in the preamble of the CY 2014 PFS final rule with comment period (78 FR 74780 through 74781) for groups of physicians should be the same as the regulation text at § 414.1270(b)(5).

Comment: Several commenters, citing the Secretary’s statutory obligation, supported our proposal to apply the VM in the CY 2017 payment adjustment year to solo practitioner physicians and to groups of physicians with two or more eligible professionals. Other commenters opposed our proposed policy notwithstanding the statutory obligation to apply the VM to all physicians and groups of physicians beginning not later than January 1, 2017. Commenters stated that we should delay the application of the VM to all physicians, either through selective implementation or requesting that Congress amend the statute. Some commenters stated that, due to provider resource constraints, lack of access to adequate technical support, and potential lack of understanding of the information provided through the Physician Feedback Program, we should postpone the extension of the VM to smaller group practices and solo practitioners. Some commenters suggested that the VM would negatively impact physicians, especially given the proposed increase in the amount of payment at risk for CY 2017.

Response: We disagree that the VM’s application to smaller groups and solo practitioners should be delayed. In addition to the statutory requirement to apply the VM to all physicians and groups of physicians beginning not later than January 1, 2017, the application of the VM to all physician groups and solo practitioners is essential to our ongoing efforts to encourage improvement in the quality and efficiency of care provided to Medicare beneficiaries and should

not be delayed. The literature highlights that the majority of patients receive care in group practices with one or two physicians¹⁶ and that historically, smaller group practices have participated in quality improvement programs at lower rates than larger group practices.¹⁷ Recent research also concludes that EHR-enabled small practices responded to incentives to improve quality of care on process and intermediate-outcome measures.¹⁸ For these reasons, we believe that the application of the VM to smaller group practices and solo practitioners has the potential to incentivize increased participation in quality reporting and quality improvement activities and that smaller groups and solo practitioners have the potential to perform well under the VM.

The application of the VM to groups of two to nine eligible professionals and to solo practitioners in CY 2017 is consistent with our principle to focus on a gradual implementation of the VM. The financial impact of applying the VM to groups of two to nine eligible professionals and to solo practitioners will be eased since, we are finalizing a policy to hold them harmless from any downward payment adjustments under quality-tiering in CY 2017 (as discussed in section III.N.4.c.) and also finalizing a smaller downward payment adjustment under the VM for these groups and solo practitioners that are in Category 2 in CY 2017 (as discussed in section III.N.4.f below). Please note that in section III.N.4.b of this final rule with comment period, we are finalizing that the VM will apply to nonphysician eligible professionals in groups subject to the VM and to nonphysician eligible professionals who are solo practitioners beginning in the CY 2018 payment adjustment period.

Comment: Several commenters stated that CMS should ensure that the quality and cost measures are reliable and valid for small practices and solo practitioners before expanding the VM to all physicians.

Response: Since the inception of the VM program, we have committed to establish a payment modifier that relies on a focused core set of measures appropriate to each specific provider category that reflects the level of care

and the most important areas of service and measures for that provider (77 FR 69306). Analysis of the Physician Feedback Program confirms that the measures on which the VM is based are highly reliable, especially those that are self-reported.¹⁹ As stated in the proposed rule (79 FR 40494), we will be basing the quality of care composite on the PQRS measures selected, and reported on, by the groups (or the eligible professionals in the groups) and the solo practitioners, which enables us to recognize the diversity of reporting options for individuals and groups under the PQRS program and provide flexibility on the data they report for quality measures under the PQRS. This also allows these groups and solo practitioners the opportunity to choose measures that are relevant to their patient populations and consistent with clinical practice and high quality care. Moreover, our policy will mitigate any unintended consequences of the VM payment adjustment on smaller groups by holding harmless solo practitioner physicians and physicians in groups with two to nine eligible professionals from any downward payment adjustments under quality-tiering in CY 2017 (see section III.N.4.c of this final rule with comment period).

We conducted an additional analysis of the cost measures for the VM, using our specialty benchmarking methodology and found the per capita cost measures to be reliable for solo practitioners and groups of two or more eligible professionals. That analysis may be found at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/ValueBasedPaymentModifier.html>.

Comment: Some commenters expressed concern about the VM’s impact on providers who treat high-cost patients and on certain specialties, such as anesthesiology, for which few quality measures are available.

Response: The VM program continues to believe in the importance of stakeholder engagement for establishing quality metrics. To that end, we engage the National Quality Forum to pursue national endorsement of measures used in PQRS and the VM program. We are committed to using PQRS as the foundation for measurement of the performance rates for solo practitioner physicians and groups of physicians subject to the VM (77 FR 69314). Moreover, we recognized early in the

¹⁶ Sowmya R Rao, et al. Electronic health records in small physician practices: availability, use, and perceived benefits. *J. Am. Med. Information Ass’n.* 2011. 18, 271–275.

¹⁷ Anne-Marie J. Audet, et al. Measure, Learn, And Improve: Physicians’ Involvement in Quality Improvement. *Health Affairs.* 2005. 24,843–853.

¹⁸ Naomi S. Bardach, et al., Effect of Pay-for-Performance Incentives on Quality of Care in Small Practices With Electronic Health Records. *J. Amer. Med. Ass’n.* 2013. 310,1051–1059.

¹⁹ Mathematica Policy Research, Experience Report for the Performance Year 2012 Quality and Resource Use Reports (January 8, 2014), available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/2012-QRUR_Experience_Report.pdf.

VM program that the PQRS may not provide specialists and sub-specialists the flexibility to report on measures that are relevant to their unique patient panels. As discussed later, in section III.N.4.h, in previous rulemakings, we have committed to expanding the specialty measures available in the PQRS in order to more accurately measure the performance on quality of care furnished by specialists. We also reaffirm our commitment to using measures of performance across specialties that are reliable and valid for the VM program (77 FR 69315; 78 FR 74773).

Physicians have sufficient flexibility to choose the quality reporting method—PQRS GPRO web-interface, claims, registries, qualified clinical data registries, and EHR reporting mechanisms, as well as the measures on which to report information. The expansion of the GPRO to registries in 2013 and to EHRs in 2014 allowed sub-specialists to participate in PQRS as members of a group practice, such that the group could report data on measures of broad applicability (77 FR 69315). The claims-based outcome measures used in the VM afford groups and solo practitioners an additional opportunity to earn a quality composite score that is above average. Where a group or solo practitioner falls in Category 1 under the VM (that is, meets the criteria to avoid the CY 2017 PQRS payment adjustment), but the group or solo practitioner does not have at least 20 cases for each PQRS measure on which it reports as required for inclusion in the quality composite of the VM, the group or solo practitioner's quality composite score would be based on the three claims-based outcome measures described at § 414.1230, provided that the group or solo practitioner has at least 20 cases for at least one of the claims-based outcome measures.

In addition, as discussed in section III.N.4.h of this final rule with comment period, eligible professionals and groups should note that PQRS has a Measure Applicability Validation (MAV) process. MAV determines PQRS incentive eligibility or potential applicability of the payment adjustment for eligible professionals and groups reporting less than nine measures across three domains or nine or more across less than three domains. We recommend that commenters refer to the Measure Application Validation (MAV) Process to alleviate concerns that lack of applicable measures would result in an automatic downward adjustment under the VM. http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2014_

PQRS_Claims_MeasureApplicabilityValidation_12132013.zip. Also, please refer to section III.K.2 of this final rule with comment period for the final 2017 policies for MAV and the criteria for satisfactory reporting for the 2017 PQRS payment adjustment.

Comment: Commenters cited that solo practitioners and groups with 2 to 24 eligible professionals, who received a QRUR in fall 2014, will have a short period of time to analyze their performance data and to prepare for the CY 2015 performance period.

Response: On September 30, 2014, we made Quality and Resource Use Reports (QRURs) available to all group of physicians and physicians who are solo practitioners based on their performance in CY 2013. As we stated in the CY 2015 proposed rule (79 FR 40494–95), we believe that we have provided small groups and solo practitioners sufficient time to understand how the VM works and how to participate in the PQRS. We are sensitive to groups and solo practitioners who may need adequate lead time to understand the impact of the beneficiary attribution method used for the VM. At the time that we made our proposal to apply the VM to solo practitioners and groups of 2 to 25 EPs, available research suggested that the information provided in the QRURs is relevant to solo practitioners and groups for future quality improvement efforts. Published literature suggests that, of the beneficiaries assigned in one year to a group practice under the Shared Savings Program attribution rule, which is substantially similar to the one used in the VM program—80 percent were assigned to that same group practice the following year.²⁰ In response to commenters' concerns, we also conducted an additional analysis using the VM attribution methodology and determined that, of the beneficiaries assigned to a given TIN for the five cost and 3 outcome measures included in the VM for 2017, approximately 76% were assigned to the same TIN for these measures, in both 2012 and 2013.

More importantly, we believe our final policy to hold harmless groups with two to nine eligible professionals and solo practitioners from any downward payment adjustments under quality-tiering in CY 2017 would likely mitigate unintended consequences that could occur (see section III.N.4.c of this final rule). We note that in the 2013 QRUR Experience Report, which will be released in the next few months, we will

provide a detailed analysis of the impact of the 2015 VM policies on groups of 100 or more eligible professionals subject to the VM in CY 2015, including findings based on the data contained in the 2013 QRURs for all groups of physicians and solo practitioners.

Comment: Several commenters believed that physicians had little experience with the PQRS program and physicians generally do not understand the methodology used to calculate the VM and therefore urged CMS to increase its outreach and education efforts. One commenter urged CMS to publicly share the VM methodology, as well as the results of the reliability and validity testing of the measures used in the calculation of the VM.

Response: In response to the comments about physicians not being familiar with the PQRS program or not understanding the methodology used to calculate the VM, we strongly encourage physicians to proactively educate themselves about the PQRS and VM programs by visiting the PQRS Web site <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html> and VM/QRUR Web site <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/index.html>. The PQRS Web site contains detailed information about how groups and individual eligible professionals can participate in the PQRS program, including information on how to avoid the PQRS payment adjustment. The VM/QRUR Web site (<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/index.html>) contains information on the VM policies for each applicable payment adjustment year, including detailed information on the methodology used to calculate the CY 2015 VM shown in the CY 2013 QRURs and how to use the information contained in the QRURs. We note that we work with medical and specialty associations throughout the year to educate them about the PQRS and VM programs and the QRURs. Further outreach will be also be undertaken by our Quality Improvement Organizations (QIOs), who will provide technical assistance to physicians and groups of physicians in an effort to help them improve quality and consequently, performance under the VM program.

As we expand the application of the VM to all physicians, we will continue to monitor the VM program and continue to examine the characteristic of those groups of physicians and solo practitioners that could be subject to an upward or downward payment adjustment under our quality-tiering

²⁰ J. Michael McWilliams, et al. Outpatient Care Patterns and Organizational Accountability in Medicare. 2014. 174,938–945.

methodology to determine whether our policies create anomalous effects in ways that do not reflect consistent differences in performance among physicians and physician groups.

After considering the public comments, we are finalizing the proposal and regulation text at § 414.1210(a)(3) that, beginning with the CY 2017 payment adjustment period, the VM will apply to physicians in groups with two or more eligible professionals and to physicians who are solo practitioners based on the performance period described at § 414.1215. We are finalizing the definition of a “solo practitioner” at § 414.1205 and amending the regulations under subpart N to add references to solo practitioners. We are also finalizing our proposal and the regulation text at § 414.1270(c)(5) that beginning in CY 2017 a group or solo practitioner will receive a cost composite score that is classified as “average” under the quality-tiering methodology if the group or solo practitioner does not have at least one cost measure with at least 20 cases. We are also finalizing our proposal to clarify that the description of this policy in the preamble of the CY 2014 PFS final rule with comment period (78 FR 74780 through 74781) for groups of physicians should be the same as the regulation text at § 414.1270(b)(5).

b. Application of the VM to Nonphysician EPs

As noted above, section 1848(p) of the Act requires that we establish the VM and apply it to items and services furnished under the PFS beginning on January 1, 2015, for specific physicians and groups of physicians the Secretary determines appropriate, and beginning not later than January 1, 2017, for all physicians and groups of physicians. Section 1848(p)(7) of the Act provides the Secretary discretion to apply the VM on or after January 1, 2017 to eligible professionals as defined in section 1848(k)(3)(B) of the Act. As previously finalized in the CY 2013 PFS final rule with comment period, in payment adjustment years CY 2015 and CY 2016, we will apply the VM to Medicare payments for items and services billed under the PFS by physicians in groups (as identified by their Medicare-enrolled TIN) subject to the VM, but not to the other eligible professionals that also may bill under the TIN (77 FR 69312). We finalized in the CY 2013 PFS final rule with comment period (77 FR 69307 through 69310) that physicians, as defined in section 1861(r) of the Act, include doctors of medicine or osteopathy, doctors of dental surgery or

dental medicine, doctors of podiatric medicine, doctors of optometry, and chiropractors.

In section III.N.4.a of this final rule with comment period, we finalized our proposal to apply the VM in the CY 2017 payment adjustment period and each subsequent calendar year payment adjustment period to physicians in groups of physicians with two or more eligible professionals and to physicians who are solo practitioners as required by section 1848(p)(4)(B)(iii)(II) of the Act.

In the CY 2015 PFS proposed rule, based on the Secretary’s discretion under section 1848(p)(7) of the Act, we proposed to apply the VM beginning in the CY 2017 payment adjustment period to all of the eligible professionals in groups with two or more eligible professionals and to eligible professionals who are solo practitioners (79 FR 40495–40496). That is, we proposed to apply the VM beginning in CY 2017 to the items and services billed under the PFS by all of the physicians and nonphysician eligible professionals who bill under a group’s TIN. We proposed to apply the VM beginning in CY 2017 to groups that consist only of nonphysician eligible professionals (for example, groups with only nurse practitioners or physician assistants). We also proposed to modify the definition of “group of physicians” under § 414.1205 to also include the term “group” to reflect these proposals. We also proposed to apply the VM beginning in CY 2017 to nonphysician eligible professionals who are solo practitioners. Additionally, we proposed that physicians and nonphysician eligible professionals would be subject to the same VM policies established in earlier rulemakings and under 42 CFR part 414, subpart N. For example, nonphysician eligible professionals would be subject to the same amount of payment at risk and quality-tiering policies as physicians. We proposed to modify the regulations under 42 CFR part 414, subpart N, accordingly.

We finalized in the CY 2013 PFS final rule with comment period (77 FR 69307 through 69310) that, for purposes of establishing group size, we will use the definition of an eligible professional as specified in section 1848(k)(3)(B) of the Act. This section defines an eligible professional as any of the following: (1) A physician; (2) a practitioner described in section 1842(b)(18)(C) of the Act: Physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse-midwife, clinical social worker, clinical psychologist, registered

dietician, or nutrition professional; (3) a physical or occupational therapist or a qualified speech-language pathologist; or (4) a qualified audiologist.

Beginning CY 2017, under our proposal, the VM would apply to all of the eligible professionals, as specified in section 1848(k)(3)(B) of the Act, that bill under a group’s TIN based on the TIN’s performance during the applicable performance period. During the payment adjustment period, all of the nonphysician eligible professionals who bill under a group’s TIN would be subject to the same VM that would apply to the physicians who bill under that TIN.

This proposal was consistent with our stated principle that the VM should focus on shared accountability (77 FR 69307). We continue to believe that the VM can facilitate shared accountability by assessing performance at the group practice level and by focusing on the total costs of care, not just the costs of care furnished by an individual physician.

Moreover, section 1848(p)(5) of the Act requires us to, as appropriate, apply the VM “in a manner that promotes systems-based care.” We stated in the CY 2013 PFS proposed rule that, in this context, systems-based care is the processes and workflows that (1) make effective use of information technologies, (2) develop effective teams, (3) coordinate care across patient conditions, services, and settings over time, and (4) incorporate performance and outcome measurements for improvement and accountability.²¹ (77 FR 44996) We stated in the CY 2015 PFS proposed rule, we believe that applying the VM to all of the eligible professionals in a group, rather than only the physicians in the group, would enhance the group’s ability and resources to redesign processes and workflows to achieve these objectives and furnish high-quality and cost-effective clinical care with greater care coordination (79 FR 40496).

As mentioned above, we also proposed to apply the VM to groups that consist only of nonphysician eligible professionals, as well as solo practitioners who are nonphysician eligible professionals beginning in CY 2017 (79 FR 40496). Consistent with the application of the VM to groups of

²¹ Johnson JK, Miller SH, Horowitz SD. Systems-based practice: Improving the safety and quality of patient care by recognizing and improving the systems in which we work. In: Henriksen K, Battles JB, Keyes MA, Grady ML, editors. *Advances in Patient Safety: New Directions and Alternative Approaches*, Vol 2: Culture and Redesign. AHRQ Publication No. 08–0034–2. Rockville, MD: Agency for Healthcare Research and Quality; August 2008. p. 321–330.

physicians and groups that contain both physicians and nonphysician EPs, the quality of care composite for groups that consist only of nonphysician EPs and solo practitioner nonphysician EPs would be based on the quality data submitted under the PQRS at the group or individual level in accordance with our existing policy. To the extent we are able to attribute beneficiaries to these groups and solo practitioners under the attribution methodology proposed in section III.N.4.j of the proposed rule to calculate cost measures, we proposed to calculate the cost composite using those cost measures. If a cost composite could not be calculated for a group or solo practitioner, then we proposed to classify the group or solo practitioner's cost composite as "average" as specified in § 414.1270. We solicited comments on all of our proposed policies for applying the VM to nonphysician eligible professionals beginning in CY 2017.

The following is summary of the comments we received on all of our proposed policies for applying the VM to nonphysician eligible professionals beginning in CY 2017.

Comment: Several commenters supported our proposal to apply the VM to nonphysician eligible professionals beginning in CY 2017. These commenters stated that the proposal would support the goal of shared accountability and urged CMS to include their cost and quality data in the QRURs. Some of the commenters wanted nonphysician eligible professionals to be held harmless from any downward payment adjustments under the VM.

Most of the commenters urged CMS to delay implementation of the VM for nonphysician eligible professionals and suggested that CMS adopt a phased approach that gives nonphysician eligible professionals more time to understand and prepare for the implementation of the VM. One commenter was specifically concerned about nonphysician eligible professionals who are solo practitioners or in groups with two to nine eligible professionals not having time to prepare for the implementation of the VM. Commenters expressed concern that nonphysician eligible professionals have not been sufficiently prepared for the VM because: prior PFS rules did not indicate that nonphysician eligible professionals may be included in the VM in the future; nonphysician eligible professional groups have not yet received a QRUR; nonphysician eligible professionals have not received targeted education regarding application of the VM to them; and the proposal does not

allow nonphysician eligible professionals the same phased-in approach to the VM that CMS provided to physician groups. One commenter recommended that CMS not apply the VM to nonphysician eligible professionals until CMS adopts meaningful specialty designations. Other commenters indicated that some nonphysician eligible professionals groups will not be attributed cost measures since they do not bill evaluation and management codes. A few commenters were concerned about the low participation rates of nonphysician eligible professionals in the PQRS program. A few commenters proposed a phased-in approach for implementation of the VM for nonphysician eligible professionals, which they stated would be consistent with the implementation of the VM for physician groups.

Response: We agree with the commenters that nonphysician eligible professionals would benefit from additional time to become familiar with participation in the PQRS program and the VM methodology. Therefore, we are not finalizing our proposal to apply the VM beginning in the CY 2017 payment adjustment period to nonphysician eligible professionals in groups with two or more eligible professionals and to nonphysician eligible professionals who are solo practitioners. Instead, we are finalizing that we will apply the VM beginning in the CY 2018 payment adjustment period to nonphysician eligible professionals in groups with two or more eligible professionals and to nonphysician eligible professionals who are solo practitioners. We added paragraph (a)(4) to § 414.1210 to reflect this policy. We note that in the CY 2015 PFS proposed rule, we did not propose a performance period for the CY 2018 payment adjustment period for the VM. The performance periods we have established in prior rulemaking for the VM have been two calendar years prior to the beginning of the payment adjustment year (for example, CY 2013 was the performance period for the VM applied in CY 2015). We expect to propose the performance period for the CY 2018 payment adjustment period for the VM in the CY 2016 PFS proposed rule.

We believe that delaying the implementation of the VM to nonphysician eligible professionals until CY 2018 is consistent with our stated objective to focus on gradual implementation of the VM. The delay would also provide additional time for nonphysician eligible professionals to learn about how to participate in the PQRS program and to become

knowledgeable about the policies for calculating the VM. Information about the VM is available on the VM/QRUR Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/index.html>.

Under our final policy, we will apply the VM beginning in CY 2018 to the items and services billed under the PFS by all of the physicians and nonphysician eligible professionals who bill under a group's TIN. We are finalizing that we will apply the VM beginning in CY 2018 to groups that consist only of nonphysician eligible professionals (for example, groups with only nurse practitioners or physician assistants). Beginning in CY 2018, the VM will apply to all of the eligible professionals, as specified in section 1848(k)(3)(B) of the Act, that bill under a group's TIN based on the TIN's performance during the applicable performance period. During the payment adjustment period, all of the nonphysician eligible professionals who bill under a group's TIN will be subject to the same VM that will apply to the physicians who bill under that TIN. We are finalizing the proposed modification to the definition of "group of physicians" under § 414.1205 to also include the term "group" to reflect these final policies. We are also finalizing the policy to apply the VM beginning in CY 2018 to nonphysician eligible professionals who are solo practitioners.

Additionally, we are finalizing that beginning in CY 2018, physicians and nonphysician eligible professionals will be subject to the same VM policies established in earlier rulemakings and under subpart N. For example, nonphysician eligible professionals will be subject to the same amount of payment at risk and quality-tiering policies as physicians. We are finalizing the proposed modifications to the regulations under subpart N accordingly.

However, since CY 2018 will be the first year that groups that consist only of nonphysician eligible professionals and solo practitioners who are nonphysician eligible professionals will be subject to the VM, we are finalizing a policy to hold these groups and solo practitioners harmless from downward adjustments under the quality-tiering methodology in CY 2018. We will add regulation text under § 414.1270 to reflect this policy when we establish the policies for the VM for the CY 2018 payment adjustment period in future rulemaking.

c. Approach to Setting the VM Adjustment Based on PQRS Participation

In the CY 2014 PFS final rule with comment period (78 FR 74767–74768), we adopted a policy to categorize groups of physicians subject to the VM in CY 2016 based on a group's participation in the PQRS. Specifically, we categorize groups of physicians eligible for the CY 2016 VM into two categories. Category 1 includes groups of physicians that (a) meet the criteria for satisfactory reporting of data on PQRS quality measures through the GPRO for the CY 2016 PQRS payment adjustment or (b) do not register to participate in the PQRS as a group practice in CY 2014 and that have at least 50 percent of the group's eligible professionals meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals for the CY 2016 PQRS payment adjustment, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS-qualified clinical data registry for the CY 2016 PQRS payment adjustment. For a group of physicians that is subject to the CY 2016 VM to be included in Category 1, the criteria for satisfactory reporting (or the criteria for satisfactory participation, if the PQRS-qualified clinical data registry reporting mechanism is selected) must be met during the CY 2014 reporting period for the PQRS CY 2016 payment adjustment. For the CY 2016 VM, Category 2 includes those groups of physicians that are subject to the CY 2016 VM and do not fall within Category 1. For those groups of physicians in Category 2, the VM for CY 2016 is -2.0 percent.

We proposed to use a similar two-category approach for the CY 2017 VM based on participation in the PQRS by groups and solo practitioners (79 FR 40496). To continue to align the VM with the PQRS and accommodate the various ways in which EPs can participate in the PQRS, for purposes of the CY 2017 VM, we proposed that Category 1 would include those groups that meet the criteria for satisfactory reporting of data on PQRS quality measures via the GPRO (through use of the web-interface, EHR, or registry reporting mechanisms, as proposed in section III.K of the proposed rule) for the CY 2017 PQRS payment adjustment. Our proposed criteria for satisfactory reporting of data on PQRS quality measures via the GPRO for the PQRS payment adjustment for CY 2017 are described in section III.K of the proposed rule. We also proposed to include in Category 1 groups that do not register to participate in the PQRS as a

group practice participating in the PQRS group practice reporting option (GPRO) in CY 2015 and that have at least 50 percent of the group's eligible professionals meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals (through the use of claims, EHR, or registry reporting mechanism,) for the CY 2017 PQRS payment adjustment, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS-qualified clinical data registry for the CY 2017 PQRS payment adjustment, all as proposed in section III.K of the proposed rule. We noted that these proposals are consistent with the policies for inclusion in Category 1 as established for the CY 2016 VM (78 FR 74767 through 74768). We would maintain the 50 percent threshold for the CY 2017 VM as we expand the application of the VM to all groups and solo practitioners in CY 2017. Our proposed criteria for satisfactory reporting by individual eligible professionals for the claims, EHR, and registry reporting mechanisms and for satisfactory participation in a qualified clinical data registry for the CY 2017 PQRS payment adjustment are described in section III.K of the proposed rule. Lastly, we proposed to include in Category 1 those solo practitioners that meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals (through the use of claims, registry, or EHR reporting mechanism) for the CY 2017 PQRS payment adjustment, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS-qualified clinical data registry for the CY 2017 PQRS payment adjustment, all as proposed in section III.K of the proposed rule. Category 2 would include those groups and solo practitioners that are subject to the CY 2017 VM and do not fall within Category 1. As discussed in the proposed rule (79 FR 40505), for CY 2017, we proposed to apply a -4.0 percent VM to groups with two or more eligible professionals and solo practitioners that fall in Category 2. We solicited comment on these proposals.

The following is summary of the comments we received on these proposals.

Comment: A number of commenters supported our proposal to continue to account for eligible professionals that participate in the PQRS as individuals in the determination of groups and solo practitioners that would be in Category 1. One commenter indicated that our proposals allow groups to have the flexibility to choose a PQRS reporting mechanism that best fits the practice.

One commenter did not support the use of both group and individual reporting mechanisms to determine whether a group falls in Category 1, indicating that it makes comparisons among groups that choose to report as a group compared to a group whose eligible professionals report as individuals inequitable.

Response: We appreciate commenters' support for our proposal to provide a way to combine individually reported PQRS measures into a group score for purposes of the CY 2017 VM. In response to the commenter's concern about the use of the individual reporting mechanisms in the VM, we believe that the use of both the individually reported PQRS measures and the PQRS GPRO measures to calculate the quality composite of the VM recognizes recognize the diversity of physician practices and the various measures used to assess quality of care furnished by these practices. As we stated in the CY 2014 PFS final rule with comment period (78 FR 74767), one of the principles governing our implementation of the VM is to align program requirements to the extent possible. Thus, we expect to continue to align the VM with the PQRS program requirements and reporting mechanisms to ensure physicians and groups of physicians report data on quality measures that reflect their practice.

Furthermore, we do not believe that comparing quality composite scores based on PQRS GPRO measures or individually reported PQRS measures would create inequities because a group's performance reflects the underlying eligible professionals on whose behalf the group reports and the quality measure benchmarks are inclusive of data gathered through both PQRS GPRO and individually-reported PQRS measures. Lastly, we note that the inclusion of individual PQRS measure in the VM provides an additional mechanism and reduces additional reporting burden for groups that are subject to the VM and do not report under the PQRS as a group to avoid an automatic VM downward payment adjustment.

After consideration of the comments received, and for the reasons stated previously, we are finalizing the two-category approach for the CY 2017 VM based on participation in the PQRS by groups and solo practitioners as proposed. For purposes of the CY 2017 VM, Category 1 will include those groups that meet the criteria for satisfactory reporting of data on PQRS quality measures via the GPRO (through use of the web-interface, EHR, or registry reporting mechanism, as

finalized in section III.K of this final rule with comment period) for the CY 2017 PQRS payment adjustment. Our final criteria for satisfactory reporting of data on PQRS quality measures via the GPRO for the PQRS payment adjustment for CY 2017 are described in Table 51 in section III.K of this final rule with comment period. We also are finalizing to include in Category 1 groups that do not register to participate in the PQRS as a group practice participating in the PQRS GPRO in CY 2015 and that have at least 50 percent of the group's eligible professionals meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals (through the use of claims, EHR, or registry reporting mechanism) for the CY 2017 PQRS payment adjustment, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS-qualified clinical data registry for the CY 2017 PQRS payment adjustment, all as finalized in Table 50 in section III.K of this final rule with comment period. Our final criteria for satisfactory reporting by individual eligible professionals for the claims, EHR, and registry reporting mechanisms and for satisfactory participation in a qualified clinical data registry for the CY 2017 PQRS payment adjustment are described in section III.K of this final rule with comment period. Lastly, we are finalizing to include in Category 1 those solo practitioners that meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals (through the use of claims, registry, or EHR reporting mechanism) for the CY 2017 PQRS payment adjustment, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS-qualified clinical data registry for the CY 2017 PQRS payment adjustment, all as finalized in Table 50 in section III.K of this final rule with comment period. Category 2 will include those groups and solo practitioners that are subject to the CY 2017 VM and do not fall within Category 1. We will continue to explore how to include additional data for specialists, including potentially incorporating Hospital VBP Program performance into the VM, as discussed in section III.N.4.k of this final rule with comment period. We would adopt any such changes through future notice and comment rulemaking. As discussed in section III.N.4.f of this final rule with comment period, for CY 2017, we are finalizing policies to (1) apply a -4.0 percent VM to groups with 10 or more eligible professionals that fall in Category 2, and (2) apply a -2.0 percent VM to groups with two to nine

eligible professionals and solo practitioners that fall in Category 2.

For a group and a solo practitioner subject to the CY 2017 VM to be included in Category 1, the criteria for satisfactory reporting (or the criteria for satisfactory participation, in the case of solo practitioners and the 50 percent option described above for groups) must be met during the reporting periods occurring in CY 2015 for the CY 2017 PQRS payment adjustment. As noted in section III.5.g of this final rule with comment period earlier, CY 2015 is the performance period for the CY 2017 payment adjustment period for the VM.

In the CY 2014 PFS final rule with comment period (78 FR 74768–74770), we finalized that the quality-tiering methodology will apply to all groups in Category 1 for the VM for CY 2016, except that groups of physicians with between 10 and 99 eligible professionals would be subject only to upward or neutral adjustments derived under the quality-tiering methodology, while groups of physicians with 100 or more eligible professionals would be subject to upward, neutral, or downward adjustments derived under the quality-tiering methodology. In other words, we finalized that groups of physicians in Category 1 with between 10 and 99 eligible professionals would be held harmless from any downward adjustments derived from the quality-tiering methodology for the CY 2016 VM.

For the CY 2017 VM, we proposed to continue a similar phase-in of the quality-tiering based on the number of eligible professionals in the group (79 FR 40497). We proposed to apply the quality-tiering methodology to all groups and solo practitioners in Category 1 for the VM for CY 2017, except that groups with two to nine eligible professionals and solo practitioners would be subject only to upward or neutral adjustments derived under the quality-tiering methodology, while groups with 10 or more eligible professionals would be subject to upward, neutral, or downward adjustments derived under the quality-tiering methodology. That is, we proposed that solo practitioners and groups with two to nine eligible professionals in Category 1 would be held harmless from any downward adjustments derived from the quality-tiering methodology for the CY 2017 VM. Accordingly, we proposed to revise § 414.1270 to reflect these proposals. We believe this approach would reward groups and solo practitioners that provide high-quality/low-cost care, reduce program complexity, and would also fully engage groups and solo

practitioners into the VM as we complete the phase-in of the VM in CY 2017. We solicited comments on these proposals.

We stated in the CY 2015 PFS proposed rule (79 FR 40497) that we believe it is appropriate to hold groups with two to nine eligible professionals and solo practitioners in Category 1 harmless from any downward adjustments under the quality-tiering methodology, which is similar to the policy we apply to groups with between 10 and 99 eligible professionals during the first year the VM applies to them (CY 2016). We noted that we anticipate applying the CY 2018 VM with both upward and downward adjustments based on a performance period of CY 2016 to all groups and solo practitioners, and therefore, we would make proposals in future rulemaking accordingly.

We stated that, for groups with between 10 and 99 eligible professionals, we believe it is appropriate to begin both the upward and the downward payment adjustments under the quality-tiering methodology for the CY 2017 VM. As stated in the CY 2014 PFS final rule with comment period (78 FR 74769), on September 16, 2013, we made available to all groups of 25 or more eligible professionals an annual QRUR based on 2012 data to help groups estimate their quality and cost composites. As discussed in section III.N.4.a. of this final rule with comment period, in September 2014, we made available QRURs based on CY 2013 data to all groups of physicians and physicians who are solo practitioners. These QRURs contain performance information on the quality and cost measures used to calculate the quality and cost composites of the VM and show how all TINs fare under the policies established for the VM for the CY 2015 payment adjustment period. As noted above, we are considering providing semi-annual QRURs with updated cost and resource use information to groups and solo practitioners. Then, during the summer of 2015, we intend to disseminate QRURs based on CY 2014 data to all groups and solo practitioners, and the reports would show how all TINs would fare under the policies established for the VM for the CY 2016 payment adjustment period. The QRURs will also include additional information about the TINs' performance on the MSPB measure, individually-reported PQRS measures, and the specialty-adjusted cost measures.

Thus, we stated that we believe groups with between 10 and 99 eligible

professionals will have adequate data to improve performance on the quality and cost measures that will be used to calculate the VM in CY 2017. As a result, we believe it is appropriate to apply both upward and downward adjustments under the quality-tiering methodology to groups with 10 or more eligible professionals in 2017.

Based on an analysis of CY 2012 claims, we estimate that approximately 6 percent of all eligible professionals are in a Category 1 TIN that would be classified in tiers that would earn an upward adjustment by having a composite score that is at least 1 standard deviation away from the mean composite and it is statistically significant, approximately 11 percent of all eligible professionals are in a Category 1 TIN that would be classified in tiers that would receive a downward adjustment by having a composite score that is at least 1 standard deviation away from the mean composite and it is statistically significant, and approximately 83 percent of all eligible professionals are in a Category 1 TIN that would receive no payment adjustment in CY 2017. These results suggest that our quality-tiering methodology identifies a small number of groups and solo practitioners that are outliers—both high and low performers—in terms of whose payments would be affected by the VM, thus limiting any widespread unintended consequences.

We stated in the CY 2015 PFS proposed rule that we will continue to monitor the VM program and continue to examine the characteristics of those groups that could be subject to an upward or downward payment adjustment under our quality-tiering methodology to determine whether our policies create anomalous effects in ways that do not reflect consistent differences in performance among physicians and physician groups.

The following is a summary of the comments we received on these proposals.

Comment: Several commenters supported applying quality-tiering to all groups and solo practitioners. One commenter did not support the concept of quality-tiering and indicated that it should be voluntary for all practices. Most commenters strongly supported our proposal to hold harmless groups with two to nine eligible professionals and solo practitioners from downward payment adjustments in CY 2017, although one commenter suggested that CMS should apply downward adjustments to them. Some commenters supported our proposal to apply upward, neutral, or downward payment

adjustment to physician groups with 10 or more eligible professionals. However, many commenters had concerns about applying the downward adjustment to groups with 10 or more eligible professionals, since we proposed a maximum downward adjustment of -4.0 percent. A commenter indicated that there is a substantial operational difference between large practices and small practices since larger practices have more resources and revenue and are better suited to absorb downward payment adjustments under the VM. Some commenters were concerned that implementation of the downward adjustment to smaller physician practices, particularly given that the downward adjustment is slated to be -4.0 percent in 2017, may negatively impact beneficiary access to care. Other comments stated that solo practitioners and groups with two to twenty-four eligible professionals would not have a QRUR until the fall 2014 and will have little time to analyze their performance data. A number of commenters recommended more intermediate, phased-in approach to the downward adjustment such as holding harmless groups with less than 25 eligible professionals, 50 eligible professionals, or all groups regardless of size. Commenters suggested that we give only upward or neutral payment adjustments to all groups and solo practitioners or keep the CY 2016 policies in place for the CY 2017 VM. One commenter suggested that physician groups be able to file for a hardship exception with CMS in the event they face a downward adjustment under the VM. One commenter suggested that the payment adjustments under quality-tiering apply to all groups regardless of size so that primary care physicians who practice in larger groups are not disadvantaged, while another suggested that CMS should not change the program in 2017. Some commenters requested demographic information about the outliers that would receive upward or downward adjustments based on quality-tiering.

Response: We appreciate the commenters' support of our proposal to apply the quality-tiering methodology to all groups and solo practitioners in Category 1 for the VM for CY 2017 and to hold solo practitioners and groups with two to nine eligible professionals in Category 1 harmless from any downward adjustments derived from the quality-tiering methodology for the CY 2017 VM. We disagree with commenters who suggested that we should not apply upward, neutral, or downward payment adjustments

derived under the quality-tiering methodology to physician groups with 10 or more eligible professionals in CY 2017. For groups with 10 or more eligible professionals, we believe it is appropriate to apply both the upward and the downward payment adjustments under the quality-tiering methodology for the CY 2017 VM. As stated in the CY 2014 PFS final rule with comment period (78 FR 74769), on September 16, 2013, we made available to all groups of 25 or more eligible professionals an annual QRUR based on 2012 data to help groups estimate their quality and cost composites. As discussed in section III.N.a. of this final rule with comment period, in September 2014, we made available QRURs based on CY 2013 data to all groups of physicians and physicians who are solo practitioners. We believe that groups of 10 or more eligible professionals will have adequate data to improve performance on the quality and cost measures that will be used to calculate the VM in CY 2017. As a result, we believe it is appropriate to apply both upward and downward adjustments under the quality-tiering methodology to groups with 10 or more eligible professionals in 2017.

With regard to the commenters' concerns over the impact of the proposed maximum -4.0 percent downward adjustments on small practices, as discussed in section III.N.4.f of this final rule with comment period, we are finalizing a policy to apply a -2.0 percent VM to groups with two to nine eligible professionals and solo practitioners that fall in Category 2. We believe the revised policy will alleviate some of the commenters' concerns about the financial impact of applying quality-tiering to small groups and solo practitioners in CY 2017.

With regard to the suggestion that physicians in groups of 10 to 24 eligible professionals have not had sufficient experience with the quality measures used in the VM, we note that on September 30, 2014, we made QRURs available to all group of physicians and physicians who are solo practitioners based on their performance in CY 2013. Each QRUR contains the group or solo practitioner's performance information on the quality and cost measures used to calculate the quality and cost composites of the VM and show how the TIN would fare under the policies established for the VM for the CY 2015 payment adjustment period. As we stated in the CY 2015 PFS proposed rule, we believe it is appropriate to hold groups with two to nine eligible professionals and solo practitioners in Category 1 harmless from any

downward adjustments under the quality-tiering methodology, which is similar to the policy we apply to groups with between 10 and 99 eligible professionals during the first year the VM applies to them (CY 2016). For groups with between 10 and 99 eligible professionals, we believe it is appropriate to begin both the upward and the downward payment adjustments under the quality-tiering methodology for the CY 2017 VM. We believe that these groups have had sufficient time to understand how the VM works and how to participate in the PQRS. We note that the 2013 QRUR Experience Report, as described in section III.N.4.a of this final rule, will also contain additional information about the groups that were determined to have cost and/or quality performance that was significantly different than average, as determined under the policies established for the VM for the CY 2015 payment adjustment period. We reiterate our belief that the final policies will reward groups and solo practitioners that provide high-quality/low-cost care, reduce program complexity, and will also fully engage groups and solo practitioners into the VM as we complete the phase-in of the VM in CY 2017.

After considering the public comments received, we are finalizing the application of the quality-tiering methodology to all groups and solo practitioners in Category 1 for the VM for CY 2017, except that groups with two to nine eligible professionals and solo practitioners would be subject only to upward or neutral adjustments derived under the quality-tiering methodology, while groups with 10 or more eligible professionals would be subject to upward, neutral, or downward adjustments derived under the quality-tiering methodology. In other words, solo practitioners and groups with two to nine eligible professionals in Category 1 would be held harmless from any downward adjustments derived from the quality-tiering methodology for the CY 2017 VM.

d. Application of the VM to Physicians and Nonphysician Eligible Professionals That Participate in the Shared Savings Program, the Pioneer ACO Model, the CPC Initiative, or Other Similar Innovation Center Models or CMS Initiatives

We established a policy in the CY 2013 PFS final rule with comment period (77 FR 69313) to not apply the VM in CY 2015 and CY 2016 to groups of physicians that participate in the Shared Savings Program Accountable

Care Organizations (ACOs), the Pioneer ACO Model, the Comprehensive Primary Care (CPC) Initiative, or other similar Innovation Center or CMS initiatives. We stated in the CY 2014 PFS final rule with comment period (78 FR 74766) that from an operational perspective, we will apply this policy to any group of physicians that otherwise would be subject to the VM, if one or more physician(s) in the group participate(s) in one of these programs or initiatives during the relevant performance period (CY 2013 for the CY 2015 VM, and CY 2014 for the CY 2016 VM).

Although section 1848(p)(4)(B)(iii)(I) of the Act gives the Secretary discretion to apply the VM beginning on January 1, 2015 to specific physicians and groups of physicians the Secretary determines appropriate, section 1848(p)(4)(B)(iii)(II) of the Act requires application of the VM beginning not later than January 1, 2017 to all physicians and groups of physicians. Therefore, as discussed in section III.N.4.a. of this final rule with comment period, we proposed to apply the VM to all physicians in groups with two or more eligible professionals and to solo practitioners who are physicians starting in CY 2017. In section III.N.4.b of this final rule with comment period, we discussed our proposal to also apply the VM starting in CY 2017 to all nonphysician eligible professionals in groups with two or more eligible professionals and to solo practitioners who are nonphysician eligible professionals. We describe in this section how we proposed to apply the VM beginning in the CY 2017 payment adjustment period to the physicians and nonphysician eligible professionals in groups, as well as those who are solo practitioners, participating in the Shared Savings Program, Pioneer ACO Model, the CPC Initiative, or other similar Innovation Center models or CMS initiatives.

(1) Physicians and Nonphysician Eligible Professionals That Participate in ACOs Under the Shared Savings Program

(a) Application of the VM to participants in the Shared Savings Program. Beginning with the CY 2017 payment adjustment period, we proposed to apply the VM to physicians and nonphysician eligible professionals in groups with two or more eligible professionals and to physicians and nonphysician eligible professionals who are solo practitioners participating in the Shared Savings Program (79 FR 40497). Groups and solo practitioners participate in the Shared Savings

Program as part of an ACO as provided in section 1899 of the Act. Under the Shared Savings Program, an ACO may consist of multiple participating groups and solo practitioners (as identified by the ACO participants' TINs). As of April 1, 2014, there are 338 ACOs participating in the Shared Savings Program. This number includes 31 ACOs that consist of only one ACO participant TIN. The ACO submits quality data on behalf of all the ACO participant TINs in that ACO under the Shared Savings Program.

Comment: Many commenters suggested that we should continue to exempt Shared Savings Program participants from the VM. These commenters stated that because participants in the Shared Savings Program have already taken on accountability for quality improvement and cost reduction, it is unnecessary and confusing to apply the VM to these providers. Several commenters suggested that this option is available under the existing language of the statute or that, if CMS believes it does not have this authority, we should seek it from Congress. Commenters also expressed concern that applying the VM to participants in the Shared Savings Program would cause inappropriate comparisons of performance and create confusion by sending mixed signals about cost and quality benchmarks. Several of these commenters stated that organizations participating in Shared Savings Program and Pioneer ACOs are making significant investments and that they believe this further underscores the importance of allowing these groups to focus on one set of pay for performance metrics to avoid creating additional investment costs. A few commenters supported the application of the VM to Shared Savings Program participants because they believe that applying the VM broadly will encourage value-based change.

Response: We disagree with commenters who believe we should continue to exempt groups and solo practitioners who participate in the Shared Savings Program from the VM. We are required under section 1848(p)(4)(B)(iii)(II) of the Act to apply the VM to all physicians and groups of physicians no later than January 1, 2017, and we believe that alignment of these programs emphasizes the importance of quality reporting and quality measurement, for improvement of the quality of care provided to Medicare beneficiaries. We understand the concerns presented by the commenters regarding calculation of the cost and quality composites under the VM, and we address them below, in

sections III.N.4.d.1(b) and (c) of this final rule with comment period.

After considering the public comments on this proposal, we are finalizing our policy to apply the VM, beginning with the CY 2017 payment adjustment period, to physicians in groups with two or more eligible professionals and physicians who are solo practitioners that participate in an ACO under the Shared Savings Program.

We note that, in response to commenters' concerns, we are not finalizing the proposal to apply the VM to nonphysician eligible professionals in the CY 2017 payment adjustment period that participate in an ACO under the Shared Savings Program, consistent with the final policy for groups and solo practitioners that do not participate in the Shared Savings Program as discussed in section III.N.4.b of this final rule with comment period. Also, consistent with our policy discussed in section III.N.4.b to apply the VM beginning with the CY 2018 payment adjustment period to nonphysician eligible professionals who are not in an ACO under the Shared Savings Program, we will apply the VM beginning with the CY 2018 payment adjustment period to nonphysician eligible professionals in groups with two or more eligible professionals and nonphysician eligible professionals who are solo practitioners that participate in an ACO under the Shared Savings Program. We further note that, based in part on concerns identified by commenters, we are finalizing policies in sections III.N.4.d.1(b) and (c) of this final rule with comment period that take into consideration a group or solo practitioner's participation in an ACO under the Shared Savings Program during the performance period for the VM, rather than participation during the payment adjustment period for the VM as proposed.

(b) Calculation of the cost composite of the VM for Shared Savings Program participants. Beginning with the CY 2017 payment adjustment period, we proposed to classify the cost composite for the VM as "average cost" for groups and solo practitioners (as identified by the ACO's participant TINs) that participate in the Shared Savings Program during the payment adjustment period (for example, CY 2017) (79 FR 40498). We proposed to apply "average cost" to these groups and solo practitioners regardless of whether they participated in the Shared Savings Program during the performance period (for example, in CY 2015 for the CY 2017 VM). We believe that it would not be appropriate to apply the quality-tiering methodology to calculate the cost

composite for these groups and solo practitioners because of the differences in the methodology used to calculate the cost benchmarks under the Shared Savings Program and the VM. Under the Shared Savings Program, cost benchmarks are based on the actual historical Medicare fee-for-service expenditures for beneficiaries that would have been assigned to the ACO during the historical benchmark period, and are updated to reflect changes in national FFS spending; however, the cost benchmarks under the VM are based on national averages. We believe that these are significant differences in the methodology for calculating the cost benchmarks under the two programs. Consequently, we believe that any attempt to calculate the VM cost composite for groups and solo practitioners participating in the Shared Savings Program using the VM quality-tiering methodology would create two sets of standards for ACOs for their cost performance. We believe that having two sets of standards for participants in ACOs for cost performance would be inappropriate and confusing and could send conflicting messages and create conflicting incentives. We solicited comments on our proposals to classify the cost composite as "average cost" for groups and solo practitioners who participate in the Shared Savings Program during the payment adjustment period.

For groups and solo practitioners who participate in the Shared Savings Program during the performance period (for example, CY 2015), but no longer participate in the Shared Savings Program during the payment adjustment period (for example, CY 2017), we proposed to apply the quality-tiering methodology to calculate the cost composite for the VM for the payment adjustment period based on the groups' and solo practitioners' performance on the cost measures, as identified under § 414.1235, during the performance period (79 FR 40499). We stated that it would be appropriate to calculate their cost composite under the quality-tiering methodology because these groups and solo practitioners are no longer part of the Shared Savings Program during the payment adjustment period.

Comment: As noted above, many commenters expressed concern that applying the VM to ACO participants in the Shared Savings Program would cause inappropriate comparisons of performance and create confusion by sending mixed signals about cost benchmarks. Several of these commenters who were opposed to the application of the VM to Shared Savings Program ACO participants suggested

that we should continue to exempt Shared Savings Program participants from the VM, but stated that if we were to apply the VM to Shared Savings Program ACO participants, we should classify the cost composite as "average cost" because of the differing methodologies for assessing cost performance for the VM and the Shared Savings Programs. A few commenters stated that groups or solo practitioners participating in the Shared Savings Program should have their cost composite calculated without regard to participation in the Shared Savings Program and disagreed with our proposed policy because it limits the potential upward adjustment under the VM available to groups and solo practitioners participating in the Shared Savings Program.

Response: We understand the concerns presented by these commenters that calculating a cost composite for these groups and solo practitioners could cause confusion and send mixed signals. The VM and Shared Savings Programs are sufficiently different such that it would be counterproductive at this point in the programs' development to measure groups and solo practitioners using different cost measures under each program. To allow Shared Savings Program participants to focus their energy and resources on the Shared Savings Program targets for slowing expenditure growth, a different approach under the VM program for groups and physicians participating in the Shared Savings Program is appropriate. We will finalize our proposal to classify the cost composite for groups and solo practitioners participating in an ACO under the Shared Savings Program as "average cost" to avoid confusion and prevent conflicting incentives for these providers who have already committed to reducing cost growth through their participation in the Shared Savings Program. We plan to investigate the possibility of calculating a VM cost composite at the ACO level in the future, so that groups and solo practitioners in ACOs would have the opportunity to earn the full upward adjustment in the future, and we would address this issue in future rulemaking.

Comment: We received several comments objecting to our proposal to take into account a group or solo practitioner's participation in a Shared Savings Program ACO during the payment adjustment period for the VM. A few commenters did not support our proposal to apply "average cost" to groups and solo practitioners that join a Shared Savings Program ACO in the

payment adjustment period, but were not in a Shared Savings Program ACO in the performance period. These commenters pointed out that this policy could discourage groups and solo practitioners from joining an ACO if it would mean they would not receive an earned upward adjustment in the payment adjustment period. One of these commenters suggested that groups or solo practitioners should be given the option to have their cost composite calculated under the quality-tiering methodology if they were not in an ACO in the performance period. Several commenters suggested that all groups and solo practitioners should be given the opportunity to “opt in” to having their cost composite calculated regardless of whether they were in an ACO in the performance period. Another commenter objected to our proposal to apply the quality-tiering methodology to calculate the cost composite for groups and solo practitioners that participate in the Shared Savings Program in the performance period but do not participate in the Shared Savings Program during the payment adjustment period. The commenter suggested that these groups should be classified as “average cost” because they would have been working toward ACO cost benchmarks during the performance year.

Response: We are convinced by commenters who raised concerns with our proposal to consider a group or solo practitioner’s participation in a Shared Savings Program ACO during the payment adjustment period for the purpose of determining the applicability of the VM to the group or solo practitioner. We believe that commenters have accurately pointed out that Shared Savings Program ACO participants would be working toward a specified set of quality and cost metrics during the performance period, and that the performance period would therefore, best define their status as a Shared Savings Program participant for the purpose of determining the applicability of the VM during the associated payment adjustment period. We agree with the points raised in the comments about assessing a group or solo practitioner under the VM cost measures and benchmarks in the payment adjustment period if that group or solo practitioner was participating in an ACO under the Shared Savings Program in the performance period. A group or solo practitioner is unlikely to know two years in advance that it plans to leave an ACO, and we do not believe it would be appropriate to assess the

group or solo practitioner under a different set of cost measures than those that the group or solo practitioner had been working toward in the performance period as part of an ACO. As stated in our proposed rule (79 FR 40498), we believe that having two sets of standards for ACOs for cost performance would be inappropriate and confusing. We believe that the Shared Savings Program has the potential to reduce expenditure growth and improve quality and we do not want to discourage groups or solo practitioners from participating in that program (79 FR 40498). Consistent with that stated intent, and in light of the comments we received pointing out the potential conflict if we were to calculate a cost composite for groups and solo practitioners that participated in an ACO under the Shared Savings Program but did not participate in the payment adjustment period, we believe it is appropriate to apply “average cost” to all groups and solo practitioners that participate in an ACO under the Shared Savings Program in the performance period regardless of whether the group or solo practitioner remains in the ACO in the payment adjustment period. We do not, however, believe that it would be appropriate to use an “opt in” policy for groups or solo practitioners participating in Shared Savings Program ACOs. We believe that allowing groups and solo practitioners who participate in the Shared Savings Program in the performance period to “opt in” to having their cost composite calculated would conflict with our intent to avoid setting multiple financial benchmarks for these groups and solo practitioners.

After considering the public comments received, we are finalizing our policy to classify the cost composite as “average cost” for groups and solo practitioners that participate in an ACO under the Shared Savings Program. Unlike our proposed policy, which considered participation in a Shared Savings Program ACO during the payment adjustment period for the VM (for example, CY 2017), we are finalizing a policy that, if a group or solo practitioner participates in a Shared Savings Program ACO during the applicable performance period (for example, the CY 2015 performance period for the CY 2017 payment adjustment period), then that group or solo practitioner’s cost composite will be classified as “average cost,” regardless of whether the group or solo practitioner participates in a Shared Savings Program ACO during the payment adjustment period. In addition to addressing some of the concerns

raised by commenters, we believe this final policy is consistent with our existing policy for CYs 2015 and 2016, under which a group’s participation in the Shared Savings Program during the performance period (CYs 2013 and 2014, respectively) is relevant for purposes of determining whether to exempt the group from application of the VM during the relevant payment adjustment period. Further, utilizing the performance period for the purpose of determining whether the group or solo practitioner is a Shared Savings Program ACO participant eliminates the need for us to calculate preliminary payment adjustment factors prior to the beginning of the payment adjustment period, and then recalculate the payment adjustment factors after the final ACO participation list is completed, as we had proposed to do (79 FR 40506).

As requested by commenters, this final policy is also simpler than our proposal, because it does not take into account a group’s status during the payment adjustment period.

(c) Calculation of the quality composite under the VM for Shared Savings Program participants. Beginning with the CY 2017 payment adjustment period, we proposed to calculate the quality of care composite score for the VM for groups and solo practitioners who participate in an ACO under the Shared Savings Program in accordance with the following policies (79 FR 40498–40499):

- We proposed to calculate the quality of care composite score based on the quality-tiering methodology using quality data submitted by the ACO, as discussed in section III.N.4.h of this final rule with comment period, from the performance period and apply the same score to all of the groups and solo practitioners under the ACO during the payment adjustment period. In other words, using CY 2017 as an example, we proposed to calculate the quality of care composite score for the CY 2017 VM for all of the groups and solo practitioners participating in the ACO in CY 2017 based on the ACO’s CY 2015 quality data. We note that in section III.N.4.h of this final rule with comment period, we are finalizing our proposal to exclude the claims-based outcome measures identified under § 414.1230 from the calculation of the quality of care composite score for groups and solo practitioners who participate in the Shared Savings Program as described in section III.N.4.d.1 of this final rule with comment period.

- For groups and solo practitioners who participate in the ACO during the payment adjustment period (for

example, CY 2017) and either did not participate in the Shared Savings Program or were part of a different ACO during the performance period (for example, CY 2015), we proposed to calculate the quality of care composite score based on the quality-tiering methodology using the quality data submitted by the ACO from the performance period. For example, if a group or solo practitioner is in ACO 1 during CY 2017, and either was not in the Shared Savings Program or was part of ACO 2 during CY 2015, we would use ACO 1's quality data from CY 2015 to calculate the quality of care composite. This approach is consistent with our policy not to "track" or "carry" an individual professional's performance from one TIN to another TIN (see 77 FR 69308 through 69310). In other words, if a professional changes groups from TIN A in the performance period to TIN B in the payment adjustment period, we would apply TIN B's VM to the professional's payments for items and services billed under TIN B during the payment adjustment period.

- If the ACO did not exist during the performance period (for example, CY 2015), then we would not have the ACO's quality data to use in the calculation of the quality of care composite score for the payment adjustment period (for example, CY 2017). Therefore, if the ACO exists during the payment adjustment period but did not exist during the performance period, we proposed to classify the quality of care composite for all groups and solo practitioners who participate in the ACO during the payment adjustment period as "average quality" for the payment adjustment period. We proposed to apply this policy to groups and solo practitioners regardless of their status during the performance period—in other words, regardless of whether they participated in the Shared Savings Program as part of a different ACO, or did not exist during the performance period (for example, a TIN forms or newly enrolls in Medicare after the end of the performance period). We believed this proposal was appropriate since we would not have the ACO's quality data from the performance period to calculate a quality of care composite for all of the groups and solo practitioners participating in the ACO during the payment adjustment period. We noted that some of these groups and solo practitioners may have participated in the PQRS during the performance period; therefore, we would have quality data for those groups and solo practitioners. If they were part of a different ACO during the performance

period, then we would also have that ACO's quality data. We stated that we did not, however, believe that it would be appropriate to use the groups' and solo practitioners' PQRS or other ACO quality data from the performance period to calculate a quality of care composite because the groups and solo practitioners are part of a new ACO during the payment adjustment period. We stated our belief that this approach would be consistent with our policy not to "track" or "carry" an individual professional's performance from one TIN to another TIN (see 77 FR 69308 through 69310). In this case, if a TIN's status changes from the performance period to the payment adjustment period (that is, participating in ACO 2 or not participating in the Shared Savings Program in the performance period, to participating in ACO 1 in the payment adjustment period), then we proposed that we would not "track" or "carry" ACO 2's quality data or the TIN's PQRS quality data to determine the quality of care composite for groups and solo practitioners who participate in ACO 1.

- For groups and solo practitioners who participate in the Shared Savings Program during the performance period (for example, CY 2015) but no longer participate in the Shared Savings Program during the payment adjustment period (for example, CY 2017), we proposed to classify the quality of care composite as "average quality" for the VM for the payment adjustment period. Since these groups and solo practitioners were part of an ACO during the performance period, we would have the ACO's quality data from that period. We stated that we did not believe it would be appropriate to use the ACO's quality data from the performance period to calculate a quality of care composite because the groups and solo practitioners are no longer part of the ACO during the payment adjustment period. We stated this approach is also consistent with our policy not to "track" or "carry" an individual professional's performance from one TIN to another TIN (see 77 FR 69308 through 69310). Even though we proposed to classify the quality of care composite for these groups and solo practitioners as "average quality," we solicited comments on whether we should use the ACO's quality data from the performance period to calculate the quality composite for these groups and solo practitioners for the payment adjustment period.

We solicited comments on all of our proposals to calculate the quality composite for groups and solo practitioners participating in the Shared

Savings Program. We provided a summary of the proposals in the proposed rule in Table 56 using TIN A and ACO 1 and ACO 2 as examples (79 FR 40499).

Comment: As noted above, in the discussion of the cost composite, we received many comments stating that we should exempt groups and solo practitioners from the 2017 VM. Many commenters also suggested an "Innovation Pathway" approach for participants in the Shared Savings Program and Innovation Center initiatives. Under this suggested approach, groups and solo practitioners participating in the Shared Savings Program or other Innovation Center initiatives would receive "average cost" and "average quality" unless they opted to have their VM calculated. The reasoning behind this approach, provided by commenters, is to allow ACOs and the participating groups and solo practitioners to focus on one set of cost and quality benchmarks and avoid confusion predicted by some commenters. Many commenters also believe that applying the VM to these groups and solo practitioners could lead to "double counting" positive or negative performance. A few commenters stated that if we are to apply the VM to groups and solo practitioners in the Shared Savings Program, they should only be subject to a neutral or an upward adjustment. Some commenters supported our proposed policies related to cost and quality composites, and one commenter stated that if the VM is applied to these groups, they believed that only a quality composite should be calculated because they believe that ACOs are already rewarded for reducing costs. We also received comments on the specific quality measures and benchmarks that we proposed to use for the VM for groups and solo practitioners participating in the Shared Savings Program, which we address in section III.N.4.h of this final rule with comment period.

Response: We appreciate commenters' concern about the potential for conflicting incentives on cost and quality performance when applying the VM to Shared Savings Program participants given that these participants are already working toward a set of cost efficiency and quality improvement goals through the Shared Savings Program. We continue to believe, however, that it is appropriate to calculate a quality composite for groups and solo practitioners participating in the Shared Savings Program based on the ACO's quality data. We appreciate the support of

commenters who agreed that it is appropriate to calculate a quality composite for these groups and solo practitioners based on the ACO's quality data. We disagree with commenters who believe it would be inappropriate to calculate a VM for groups and solo practitioners that participate in the Shared Savings Program because this could be seen as "double counting" performance. We believe that application of the VM to providers who participate in the Shared Savings Program reinforces the importance of quality improvement and quality reporting by offering participants in the Shared Savings Program an opportunity to earn an upward adjustment for improved performance. We agree with the commenter who stated if calculating a VM for Shared Savings Program participants, we should only calculate the quality composite. However, we would like to point out that the Shared Savings Program does also reward high quality care in addition to rewarding reductions in cost growth. Unlike the differences between the methodologies for evaluating costs under the Shared Savings Program and the VM, we do not believe that the differences between the quality methodologies for these two programs will create significant confusion or conflicting incentives. Because the GPRO web interface measures are consistent across the VM and Shared Savings Program, we believe that it will not create undue burden on ACO participants or cause significant confusion to calculate a quality composite for these groups and solo practitioners. More specifically, the cost measures and cost benchmarks used to determine the cost composite under the VM are different than the methodology used to calculate financial performance under the Shared Savings Program. In contrast, the GPRO web interface quality measures used in the Shared Savings Program are the same as those used to calculate the quality composite of the VM for groups that are not in Shared Savings Program ACOs that report through GPRO. Furthermore, ACOs in the Shared Savings Program report on quality measures on behalf of all the groups and solo practitioners that participate in the ACO, which allows us to calculate a single quality composite that can be applied to all participants. We do not have this same capability for the cost composite, which would need to be calculated separately for each group or solo practitioner and thus could create conflicting incentives and add more confusion. By calculating a quality composite for groups and solo practitioners that participate in ACOs

under the Shared Savings Program we are providing an additional incentive to improve the quality of care for their beneficiaries. As stated in section III.N.4.d.1.b., where we discuss the calculation of the cost composite for Shared Savings Program ACO participants, we do not believe it would be appropriate to allow groups or solo practitioners to "opt in" to having their VM calculated based on the TIN's, rather than the whole ACO's, performance. Allowing groups or solo practitioners to "opt in" to having their own VM calculated could create conflicting incentives and competing priorities between the ACO's goals and the specific group's or solo practitioner's goals. An "opt in" policy would result in Shared Savings Program ACO participants reporting quality data outside of the ACO, which is not consistent with the policies of the Shared Savings Program.

Comment: As noted in the section III.N.4.d.1.b., we received a few comments related to scenarios in which a group or solo practitioner enters or leaves the Shared Savings Program. Commenters pointed out that applying an ACO's quality performance to groups or solo practitioners that were not in the ACO in the performance period could discourage groups and solo practitioners from joining an ACO in the payment adjustment period if it would mean they would not receive an earned upward adjustment. One commenter indicated that it would not be fair to assess a group or solo practitioner that was in the Shared Savings Program in the performance period, but is not in the payment adjustment period, without consideration of the incentives in place in the performance period. This commenter, however, did not object to the application of "average quality" to groups and solo practitioners in this situation. We also received some general comments that the many different scenarios proposed were confusing and added additional complexity to the VM program.

Response: We appreciate the comments that pointed out the potential problems with using participation during the payment adjustment period to determine the quality performance of groups and solo practitioners. As stated in the comments and responses in section III.N.4.d.1.b., we agree that using a group or solo practitioner's status in the payment adjustment period could discourage future participation in the Shared Savings Program. Consistent with our response to the cost composite comments, we believe that it would be inappropriate to ignore the quality performance of a group or solo

practitioner in the performance period because they choose to join an ACO in the payment adjustment period, as well as in the opposite scenario (if a group or solo practitioner participated in an ACO in the performance period and then left the ACO in the payment adjustment period). As discussed in our earlier response, we believe it would be appropriate to use the ACO's quality performance because the group or solo practitioner was part of the ACO during the performance period and should be assessed based on the incentives that existed during the performance period. Our proposal to consider a group or solo practitioner's participation in a Shared Savings Program ACO during the payment adjustment period was intended to be consistent with our existing policy to not "track" or "carry" an individual's performance from one TIN to another from performance period to payment adjustment period. Given the comments we received on our proposals concerning the cost and quality composites for groups and solo practitioners that participate in an ACO under the Shared Savings Program, we agree that it is preferable to consider a group or solo practitioner's participation in an ACO during the performance period to determine how the VM should be applied. Given that we would have ACO-level quality data available for group and solo practitioners that were in an ACO in the performance period, we believe this data should be used to calculate a quality composite for those groups and solo practitioners. This is consistent with the policy regarding the cost composite that we are finalizing in section III.N.4.d.1.b of this final rule with comment period, which focuses on the cost and quality performance incentives that existed for the group or solo practitioner in the performance period, not the payment adjustment period when applying the VM to groups and solo practitioners that are in the Shared Savings Program. As noted above, it is also consistent with the way in which we have determined participation in the Shared Savings Program for the 2015 and 2016 VM, based on whether the group or solo practitioner participated in the Shared Savings Program during the performance period. Further, as noted in the cost composite section III.N.4.d.1.b, utilizing the performance period for the purpose of determining whether the group or solo practitioner is a Shared Savings Program ACO participant eliminates the need for us to calculate preliminary payment adjustment factors prior to the beginning of the payment adjustment period, and then recalculate

the payment adjustment factors after the final ACO participation list is completed, as we had proposed to do (79 FR 40506). We are also convinced by commenters who stated that our proposed policies were too complex. We believe that using a TIN's participation in an ACO in the performance period to determine the cost composite, while considering the TIN's status in the payment adjustment period to determine the quality composite, would add unnecessary complexity and inconsistency, especially as new ACOs continue to be established and existing ACOs expand.

In the proposed rule (79 FR 40498), we stated that if a group or solo practitioner was in ACO 2 in the performance period and then joined ACO 1 in the payment adjustment period, we would use ACO 1's quality performance to calculate the quality composite for that group or solo practitioner. Although we did not receive specific comments on this policy, we believe that based on the other comments received and the policy we are finalizing it would no longer be appropriate to use ACO 1's quality data to calculate a quality composite for these groups and solo practitioners. Given that in all other scenarios, we are finalizing policies that we will consider the group or solo practitioner's (as identified by taxpayer identification number (TIN)) status during the performance period, rather than the payment adjustment period to determine how the group's or solo practitioner's quality and cost composite should be calculated, we also believe this is the appropriate approach for groups and solo practitioners that move between ACOs. We have previously stated our rationale for using the performance period to determine a TIN's association with an ACO and we believe that reasoning applies to this scenario as well. Furthermore, it would be unnecessarily complex to apply a different policy for groups and solo practitioners in this scenario (where the TIN is part of one ACO during the performance period and a different ACO during the payment adjustment period) than in the other scenarios previously discussed.

After considering the public comments received, we are finalizing a policy to calculate a quality of care composite score based on the quality-tiering methodology using quality data submitted by a Shared Savings Program ACO during the performance period and apply the same quality composite to all of the groups and solo practitioners, as identified by TIN, under that ACO. Unlike our proposed policy, which

considered whether a group or solo practitioner participates in a Shared Savings Program ACO during the payment adjustment period for the VM (for example, CY 2017), our final policy is if a group or solo practitioner participates in a Shared Savings Program ACO during the applicable performance period (for example, the CY 2015 performance period for the CY 2017 payment adjustment period), then that group or solo practitioner's quality composite is calculated using the ACO-level quality data from the performance period, regardless of whether the group or solo practitioner participates in a Shared Savings Program ACO during the payment adjustment period. The VM calculated under this policy will apply to all physicians billing under the group's TIN in the CY 2017 payment adjustment period, and beginning in the CY 2018 payment adjustment period, to all physician and nonphysician eligible professionals billing under the group's TIN, regardless of whether the professional was part of the group in the performance period. This is consistent with our policy for other groups subject to the VM, in that we will not "track" or "carry" an individual professional's performance from one TIN to another TIN.

Comment: Several commenters requested that we provide further guidance on how groups that leave the Shared Savings Program will be treated under the VM. Specifically one commenter suggested that we consider how we would apply the VM in situations in which an ACO dissolves mid-year and does not report quality data. The commenter stated that we should ensure that those groups and solo practitioners participating in the ACO are not subject to the automatic downward adjustment.

Response: We appreciate commenters raising these questions and concerns. We did not specifically address in the proposed rule the scenario in which a Shared Savings Program ACO does not successfully report on quality as required under the Shared Savings Program during the performance period for the VM. We clarify that we intended to adopt for groups and solo practitioners that participate in a Shared Savings Program ACO the same policy that is generally applicable to groups and solo practitioners that fail to satisfactorily report or participate under PQRS and thus fall in Category 2 and are subject to an automatic downward adjustment under the VM in CY 2017 (79 FR 40496–40497). We are finalizing this policy for groups and solo practitioners that participate in a Shared Savings Program ACO under

§ 414.1210(b)(2). Consistent with the application of the VM to other groups and solo practitioners that report under PQRS as described in section III.N.4.c, if the ACO does not successfully report quality data as required by the Shared Savings Program under § 425.504, all groups and solo practitioners participating in the ACO will fall in Category 2 for the VM and therefore will be subject to a downward payment adjustment as described in section III.N.4.f. We also plan to issue program-specific guidance to provide participants with more information about how these various situations may be addressed. Our final policy focusing on the group or solo practitioner's status in the performance period will simplify the operational issues related to determining the answers to these questions.

(d) Treatment of groups with two to nine eligible professionals and solo practitioners in the Shared Savings Program. In section III.N.4.c of this final rule with comment period, we discussed our proposal to hold groups with two to nine eligible professionals and solo practitioners who are in Category 1 harmless from any downward adjustments under the quality-tiering methodology for the CY 2017 payment adjustment period. We proposed to also hold harmless from any downward adjustments groups with two to nine eligible professionals and solo practitioners who participate in ACOs under the Shared Savings Program during the CY 2017 payment adjustment period based on their size during the performance period. We would follow our established process for determining group size, which is described at § 414.1210(c). Therefore, to the extent that a quality of care composite can be calculated for an ACO, and the cost composite would be classified as "average cost," groups with 10 or more eligible professionals participating in the Shared Savings Program would be subject to an upward, neutral, or downward payment adjustment in CY 2017, and groups with two to nine eligible professionals and solo practitioners would be subject to an upward or neutral payment adjustment in CY 2017. We also proposed that groups and solo practitioners participating in ACOs under the Shared Savings Program would be eligible for the additional upward payment adjustment of +1.0x for caring for high-risk beneficiaries, as proposed in section III.N.4.f. We proposed to modify § 414.1210 to reflect these proposals.

Comment: We did not receive any comments on these proposals specific to the Shared Savings Program. General

comments on these proposals are addressed in section III.N.4.c of this final rule with comment period.

Consistent with final policies in this final rule with comment period to use a group or solo practitioner's status in the performance period to determine participation in the Shared Savings Program, we are finalizing a policy to hold harmless from any downward adjustments groups with two to nine eligible professionals and solo practitioners who participate in ACOs under the Shared Savings Program during the performance period (for example, the CY 2015 performance period for the CY 2017 payment adjustment period) based on their size during the performance period.

We have modified § 414.1210 to reflect these final policies for application of the VM beginning with the CY 2017 payment adjustment period to groups and solo practitioners that participate in an ACO under the Shared Savings Program ACO.

(2) Physicians and Nonphysician Eligible Professionals That Participate in the Pioneer ACO Model, the Comprehensive Primary Care (CPC) Initiative, or Other Similar Innovation Center Models or CMS Initiatives

Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models to reduce Medicare, Medicaid, or Children's Health Insurance Program (CHIP) expenditures, while preserving or enhancing the quality of care furnished to beneficiaries under those programs. Therefore, all models tested by the Innovation Center would be expected to assess participating entities (for example, providers, ACOs, states) based on quality and cost performance. As noted above, we established a policy in the CY 2013 PFS final rule with comment period (77 FR 69313) to not apply the VM in CY 2015 and CY 2016 to groups of physicians that are participating in the Pioneer ACO Model, the CPC Initiative, or in other Innovation Center initiatives or other CMS programs which also involve shared savings and where participants make substantial investments to report quality measures and to furnish higher quality, more efficient and effective healthcare.

The Pioneer ACO Model and the CPC Initiative are scheduled to end on December 31, 2016. Therefore, the relevant performance periods for consideration for participants in these initiatives are CY 2015 for the CY 2017 VM payment adjustment period and potentially CY 2016 for the CY 2018 VM payment adjustment period. Under the

Pioneer ACO Model, an ACO may consist of practitioners from multiple participating groups and solo practitioners (as identified by their individual TIN/NPI combination). Thus, a group practice may consist of one or more eligible professionals who participate in the Pioneer ACO Model and other eligible professionals who do not participate in the Pioneer ACO Model. In the case of the CPC Initiative, a practice site may participate in the model even if one or more other practice sites that use the same TIN does not participate.

(a) Application of the VM to participants in the Pioneer ACO Model and CPC Initiative. Beginning with the CY 2017 payment adjustment period, we proposed to apply the VM to physicians and nonphysician eligible professionals in groups with two or more eligible professionals and to physicians and nonphysician eligible professionals who are solo practitioners who participate in the Pioneer ACO Model or the CPC Initiative during the relevant performance period in accordance with the policies described below (79 FR 40500).

Comment: The majority of comments we received stated that CMS should not apply the VM to group practices and solo practitioners participating in the Pioneer ACO Model or CPC Initiative. These comments largely mirrored the comments summarized in section III.N.4.d.1.a of this final rule with comment period regarding the application of the VM to Shared Savings Program participants. A few commenters also suggested that the application of the VM to Innovation Center initiatives should be waived under section 1115A of the Act. Additionally, one organization expressed concern that the number of varying approaches to calculating the VM in our proposed rule would be too complex to implement and may not create equitable comparisons among Pioneer, CPC, other Innovation Center model participants, and other individuals and groups under the VM program. This commenter suggested that we exempt group practices and solo practitioners who participate in the Pioneer ACO Model until that model ends. As noted in section III.N.4.d.1.a, a few commenters supported the application of the VM to as many groups and solo practitioners as possible to encourage value-based change.

Response: We are required to apply the VM to all physicians and groups of physicians beginning no later than January 1, 2017, and we believe that alignment of the VM program and the Pioneer ACO Model, CPC Initiative, and

other similar models emphasizes the importance of quality reporting and quality measurement, for improvement of the quality of care provided to Medicare beneficiaries. We understand the concerns presented by these commenters and summarized in section III.N.4.d.1 regarding calculation of the cost and quality composites under the VM, and we address them below, in section III.N.4.d.2.b of this final rule with comment period.

After considering the public comments on this proposal, we are finalizing a policy to apply the VM in the CY 2017 payment adjustment period, to physicians in groups with two or more eligible professionals in which at least one eligible professional participates in the Pioneer ACO Model or the CPC Initiative during the performance period, and to physicians who are solo practitioners that participate in the Pioneer ACO Model or the CPC Initiative during the performance period.

We note that, in response to commenters' concerns, we are not finalizing the proposal to apply the VM to nonphysician eligible professionals in the CY 2017 payment adjustment period that participate in the Pioneer ACO Model or CPC Initiative. This policy is consistent with the policy for the Shared Savings Program in the CY 2017 payment adjustment period described in section III.M.4.d.1 and for groups and solo practitioners that do not participate in these models or in the Shared Savings Program, as discussed in section III.N.4.b of this final rule with comment period.

(b) Calculation of the cost and quality composite of the VM for Pioneer ACO and CPC Initiative participants.

- For groups and solo practitioners who participate in the Pioneer ACO Model or the CPC Initiative during the performance period for the VM, we proposed policies for how we would calculate the cost and quality composites in a number of scenarios depending on whether or not all eligible professionals in the group participate in the model, whether or not the group or solo practitioner report through PQRS outside of the model, and if so, through which reporting mechanism, and whether or not the group or solo practitioner participate in the Shared Savings Program in the payment adjustment period. Additionally, we described several alternatives that we considered to the proposed policies. Specifically, we described two alternatives to Scenario 2 described in the proposed rule (79 FR 40501). Under one alternative, for groups that have some eligible professionals participating

in the model and some eligible professionals that are not participating in the model, we considered applying “average quality” without regard to any PQRS data reported outside of the model. Another alternative we considered was to apply “average quality” to groups where less than 50 percent of all eligible professionals in the group meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals or satisfactorily participate in a PQRS-qualified clinical data registry, because we would not have quality data for more than half of the group that we could use to calculate a quality composite. For a detailed description of these scenarios and proposed policies, as well as the alternatives considered, we refer readers to the proposed rule at 79 FR 40500–40504. We also provided a summary of these proposals, as Table 57 in the proposed rule (79 FR 40504).

We solicited comments on these proposals and the alternatives considered.

Comment: We received comments on our proposals for calculating the quality and cost composites for Pioneer ACO Model and CPC Initiative participants. As noted in section III.N.4.d.2.a of this final rule with comment period, most commenters did not support our proposal to apply the VM to Pioneer ACO and CPC participants in general. However, many of these commenters stated that if the VM were to be applied to these providers, then CMS should classify the cost and quality composites as average to avoid sending what they see as conflicting messages about cost and quality benchmarks. These commenters did not make any distinction between the reporting mechanism used when quality data is reported to PQRS outside of the model (for example, GPRO vs. individual reporting). Instead, they argued that we should apply average cost and average quality for all groups and solo practitioners participating in these models because they have already taken on accountability for cost and quality measures, and it would be confusing and unnecessary to hold them to a different set of measures or benchmarks. The “Innovation Pathway” suggestion referenced in the summary of comments on section III.N.4.d.1 was also recommended for groups and solo practitioners participating in the Pioneer Model and CPC Initiative. A few commenters suggested that providers participating in Pioneer or CPC should only be eligible for upward VM adjustments. Some commenters suggested that groups and solo practitioners should be able to opt-in to

having their cost and quality composites calculated as described in the proposed rule. We also received a comment indicating that providers in the Pioneer and CPC models should have their VM calculated the same as any other TIN subject to the VM.

Response: We are convinced by commenters who suggested that groups and solo practitioners in these models should be classified as “average cost” and “average quality.” In section III.N.4.d.1, we described our rationale for classifying the cost composite as “average” for groups and solo practitioners that participate in an ACO under the Shared Savings Program. Similar to the Shared Savings Program, the Pioneer ACO Model and CPC Initiative use a shared savings methodology that is significantly different than the cost measures and benchmarks used to calculate the cost composite under the VM program. Because of these significant differences, we are persuaded by commenters who stated that the calculating a cost composite for groups and solo practitioners in these models could create conflicting incentives. Moreover, it is challenging to meaningfully assess the quality performance of groups that participate in these models for purposes of calculating a quality composite for the VM given that for many of these groups, some eligible professionals in the group participate in these models while other eligible professionals within the same group do not participate (79 FR 40502). Although the Pioneer ACO Model uses the same set of quality measures as the Shared Savings Program, this quality data does not necessarily represent all eligible professionals in the group because some do not participate in the model. The CPC Initiative presents similar challenges because of groups in which only a subset of eligible professionals may be participating in the model. Because some of the groups with eligible professionals participating in these models could choose to report outside of the model through a PQRS reporting mechanism, we may have quality data for a subset of groups or for a subset of individuals within a group, depending on the reporting mechanism. The policies in our proposed rule indicated that we would make use of this quality data when available, however, as noted above, we also considered other options including applying “average quality” to certain groups. We agree that it is important for these participants to focus on the cost and quality measures within their respective models and are persuaded by

the vast majority of commenters who indicated that these policies could create conflicting incentives for model participants and several commenters who stated that they were unnecessarily complex and likely to cause confusion. We do not agree with commenters who suggested giving groups and solo practitioners an opportunity to “opt-in” for the reasons stated in response to comments on section III.N.4.d.1. We appreciate the support of commenters who agreed that applying the VM to groups and solo practitioners in these initiatives would support the VM program goals of improving quality and cost efficiency. To the extent possible, we intend to provide QRURs showing cost and, where available, quality performance on VM measures, to these groups and solo practitioners to further support the goals of the VM program.

Comment: We also received comments on our proposal to calculate the cost composite for groups and solo practitioners who are not in the Shared Savings Program or similar CMS initiative in the payment adjustment year. These commenters stated that groups and solo practitioners should be assessed based on the cost and quality incentives that were in place in the performance period, not the payment adjustment period. Under our proposed policies, we would calculate a cost composite for groups that participated in Pioneer or CPC in the performance period but did not participate in another similar initiative or the Shared Savings Program in the payment adjustment period. One commenter stated these groups and solo practitioners should be classified as average cost because at least a portion of their eligible professionals were operating under a different set of cost measures during the performance period.

Response: As noted in section III.N.4.d.1, we are persuaded by commenters who suggested that taking into account the status of the group or solo practitioner in the payment adjustment period does not fully acknowledge the incentives that existed for the group or solo practitioner in the performance period and, consistent with the approach taken for Shared Savings Program participants, we are finalizing a policy that takes into account whether a group or solo practitioner participates in the Pioneer ACO Model or CPC Initiative during the performance period for the VM. As discussed above, we believe the differences in methodology between the VM cost measures and the methodologies used to determine shared savings under the Pioneer ACO Model and the CPC Initiative are significant and that it would be inappropriate to

calculate a cost composite for these groups and solo practitioners. In the proposed rule (79 FR 40502), we stated that for groups and solo practitioners that participate in the Pioneer ACO Model or CPC Initiative in the performance period and then participate in an ACO under the Shared Savings Program in the payment adjustment period, we would use the Shared Savings Program ACO's quality data to calculate the quality composite, or classify the quality composite as average if the ACO did not exist in the performance period. We are modifying this policy such that groups or solo practitioners who participate in the Pioneer ACO Model or CPC Initiative in the performance period and then participate in an ACO under the Shared Savings Program in the payment adjustment period will also receive "average cost" and "average quality". This is consistent with the policies we are finalizing for the groups and solo practitioners that participate in an ACO under the Shared Savings Program to consider the group or solo practitioner's status during the performance period, in order to determine how the VM will be applied.

After considering the public comments, we are finalizing a policy that for solo practitioners and groups with at least one eligible professional participating in the Pioneer ACO Model or CPC Initiative during the performance period, we will classify the cost composite as "average cost" and the quality composite as "average quality" for the CY 2017 payment adjustment period. This policy is similar to the alternative to scenario 2 we considered in the proposed rule (79 FR 40501), though with a broader application to address commenters' concerns about the level of complexity in the proposals. We are not finalizing our proposals regarding the requirements for groups and solo practitioners in the Pioneer ACO Model and CPC Initiative to avoid Category 2 and the downward payment adjustment. Instead, for the CY 2017 payment adjustment period, the policy to classify the cost composite as "average cost" and the quality composite as "average quality" will apply to all solo practitioners who participate in the Pioneer ACO Model or the CPC Initiative in the performance period and all groups with at least one eligible professional who participates in the Pioneer ACO Model or the CPC Initiative in the performance period. Given the concerns about distracting from the goals of the models in which these groups and solo practitioners

participate, the complexity of determining whether groups that have some eligible professionals in the model and some who are not in the model successfully reported quality performance data, and the commenters' requests for a simpler policy, we believe this is an appropriate policy.

The VM calculated under this policy will apply to all physicians billing under the group's TIN in the CY 2017 payment adjustment period regardless of whether the physician was part of the group in the performance period. This is consistent with our policy for other groups subject to the VM, in that we will not "track" or "carry" an individual professional's performance from one TIN to another TIN.

(c) Treatment of groups of two to nine eligible professionals and solo practitioners that participate in the Pioneer ACO Model or CPC Initiative.

In section III.N.4.c of this final rule with comment period, we discussed our proposal to hold groups with two to nine eligible professionals and solo practitioners who are in Category 1 harmless from any downward adjustments under the quality-tiering methodology for the CY 2017 payment adjustment period. We proposed to also hold harmless from any downward adjustments for CY 2017 groups with two to nine eligible professionals, where one or more eligible professionals participate in the Pioneer ACO Model or the CPC, and solo practitioners who participate in the Pioneer ACO Model or the CPC during the CY 2015 performance period based on their size during the performance period. We would follow our established process for determining group size, which is described at § 414.1210(c). We also proposed that groups where one or more eligible professionals participate in the Pioneer ACO Model or the CPC during the performance period, and solo practitioners participating in the Pioneer ACO Model or the CPC during the performance period would be eligible for the additional upward payment adjustment of +1.0x for caring for high-risk beneficiaries, as proposed in section III.N.4.f below.

Comment: We did not receive comments specific to this proposal. The comments we received on our general policy to hold harmless groups of two to nine eligible professionals and solo practitioners are discussed in III.N.4.a of this final rule with comment period.

Given the modified policy we are finalizing for group practices and solo practitioners participating in the Pioneer ACO Model and CPC Initiative to classify the cost composite as "average cost" and the quality

composite as "average quality," these proposals are no longer relevant and will not be finalized.

(d) In addition, beginning with the CY 2017 payment adjustment period, we proposed to apply the VM to physicians and nonphysician eligible professionals in groups with two or more eligible professionals and to physicians and nonphysician eligible professionals who are solo practitioners who participate in other similar Innovation Center models or CMS initiatives during the relevant performance period for the VM in accordance with the proposed policies described above for the Pioneer ACO Model and the CPC Initiative. We are unable to propose an exhaustive list of the models and initiatives that would fall under this category because many of them have not yet been developed. In addition, it is possible that the timeline for implementing some of these new models and initiatives may not coincide with the timeline for rulemaking for the VM. To address these issues, we proposed to rely on the following general criteria to determine whether a model or initiative would fall in this "other similar" category and thus would be subject to the policies described above for the Pioneer ACO Model and the CPC Initiative: (1) The model or initiative evaluates the quality of care and/or requires reporting on quality measures; (2) the model or initiative evaluates the cost of care and/or requires reporting on cost measures; (3) participants in the model or initiative receive payment based at least in part on their performance on quality measures and/or cost measures; (4) potential for conflict between the methodologies used for the VM and the methodologies used for the model or initiative; or (5) other relevant factors specific to a model or initiative. We noted that a model or initiative would not have to satisfy or address all of these criteria to be included in this "other similar" category. Rather, the criteria are intended to serve as a general framework for evaluating models and initiatives with regard to the application of the VM to groups and solo practitioners who participate (79 FR 40502). We solicited public comment on these or other appropriate criteria for determining which models or initiatives we should classify as "other similar" models, for the purposes of applying the policies for the Pioneer ACO Model and the CPC Initiative described above.

Comment: We did not receive any comments on the criteria proposed to determine "other similar" models, though many of the comments received on our proposals related to the application of the VM to groups and

solo practitioners participating in the Shared Savings Program, Pioneer ACO Model, or CPC Initiative.

Response: As stated in our response to comments on the application of the VM to Pioneer ACO and CPC Initiative participants, we are convinced by commenters who suggested that we apply “average cost” and “average quality” to these groups and solo practitioners. We believe many of these “other similar” models would be testing new quality measures, reporting methods, or both, and we want to encourage innovation, including standing up new infrastructure to capture performance on quality measures that could be used in the VM program in the future.

After consideration of the comments, we are finalizing our general criteria as proposed for determining if a model or initiative should be classified as an “other similar” model or initiative. We will apply the final policies adopted for applying the VM to groups and solo practitioners that participate in the Pioneer Model or the CPC Initiative to Innovation Center models and CMS initiatives that we determine are “similar” based on these criteria.

We recognize that the policies we finalize for the Pioneer ACO Model and the CPC Initiative might not be applicable to all of the various models and initiatives that could be developed in future years. If we believe a different approach to applying the VM would be appropriate for a model or initiative, we intend to address it in future rulemaking. In addition, if we were to determine that a model or initiative falls under this “other similar” category based on the general criteria, we will provide notice to participants in the model or initiative through the methods of communication that are typically used for the model or initiative.

Additionally, consistent with our final policies for the Pioneer ACO Model and CPC Initiative, Shared Savings Program, and groups and solo practitioners that do not participate in these programs or models, we will not apply the VM to nonphysician eligible professionals in similar Innovation Center models or CMS initiatives in the CY 2017 payment adjustment period.

We modified § 414.1210 to reflect all of these policies.

In addition to the comments described above, we received a few comments that were outside the scope of what was proposed in this rule:

Comment: One commenter stated that ACOs should have an opportunity to receive confidential reports on their performance on all Medicare FFS beneficiaries—not just MSSP-attributed

beneficiaries—through the Physician Feedback Program prior to application of the VM program. This commenter also stated that CMS should reduce the administrative burden associated with the “opt out” process for data sharing for Shared Savings Program ACOs. Other commenters stated that CMS should adjust the financial benchmarks for ACOs based on VM adjustments.

Response: We appreciate the input from these commenters but believe these suggestions are outside the scope of this rule. Data sharing policies and financial benchmarking methodologies for the Medicare Shared Savings Program are described in the Final Rule for that program released in November 2011. The rule can be accessed <http://www.gpo.gov/fdsys/pkg/FR-2011-11-02/pdf/2011-27461.pdf>. Information on the Pioneer ACO Model, can be found here: <http://innovation.cms.gov/initiatives/Pioneer-ACO-Model/>.

e. Clarification Regarding Treatment of Non-assigned Claims for Non-Participating Physicians

In the CY 2013 PFS final rule with comment period in which we established a number of key policies for the VM, we stated that we had received few comments on our proposal to apply the VM to the Medicare paid amounts for the items and services billed under the PFS so that beneficiary cost-sharing or coinsurance would not be affected (77 FR 69309). These commenters generally agreed with the proposal to apply the VM to the Medicare paid amounts for the items and services billed under the PFS at the TIN level so that beneficiary cost-sharing would not be affected. Therefore, we finalized this policy and accordingly established a definition of the VM at § 414.1205 that was consistent with the proposal and the statutory requirement to provide for differential payment to a physician or a group of physicians under the fee schedule based upon the quality of care furnished compared to cost during a performance period.

We continue to believe that it is important that beneficiary cost-sharing not be affected by the VM and that the VM should be applied to the amount that Medicare pays to physicians. However, in previous rulemaking, we did not directly address whether the VM would be applied to both assigned services for which Medicare makes payment to the physician, and to non-assigned services for which Medicare makes payment to the beneficiary. Participating physicians are those who have signed an agreement in accordance with section 1842(h)(1) of the Act to accept payment on an assignment-

related basis for all items and services furnished to Medicare beneficiaries. In other words, participating physicians agree to accept the Medicare approved amount as payment in full and to charge the beneficiary only the Medicare deductible and coinsurance amount. In contrast, non-participating physicians have not signed an agreement to accept assignment for all services furnished to beneficiaries, but they can still choose to accept assignment for individual services. If they choose not to accept assignment for particular services, non-participating physicians can charge the beneficiary more than the Medicare-approved amount, up to a limit called the “limiting charge.” The limiting charge is defined at section 1848(g)(2)(C) of the Act as 115 percent of the recognized payment amount for nonparticipating physicians. In contrast, if a non-participating physician chooses to accept assignment for a service, they receive payment from Medicare at the approved amount for non-participating physicians, which is 95 percent of the fee schedule amount. Over 99 percent of Medicare physician services are billed on an assignment related basis by both participating and non-participating physicians and other suppliers, with the remainder billed as non-assigned services by non-participating physicians and other suppliers.

For assigned claims, Medicare makes payment directly to the physician. In accordance with section 1848(p)(1) of the Act and the regulations at § 414.1205 and § 414.1210(a), the VM should be applied to assigned claims. However, for non-assigned claims, the limiting charge (the amount that the physician can bill a beneficiary for a non-assigned service) would not be affected if the VM were applied to the claim. This is so, because for non-assigned claims, application of the VM would not affect the limiting charge. Rather, Medicare makes payment for the non-assigned services directly to the beneficiary and the physician receives all payment for a non-assigned service directly from the beneficiary. If the VM were to be applied to non-assigned services, then the Medicare payment to a beneficiary would be increased when the VM is positive and decreased when the VM is negative. The application of the VM to non-assigned claims would therefore directly affect beneficiaries and not physicians, contrary to our intent as discussed in previous rulemaking (77 FR 69309). On that basis, we proposed to clarify that we would apply the VM only to assigned services and not to non-assigned services starting in CY 2015 (79 FR

40504). We do not expect this proposed clarification, to not apply the VM to non-assigned claims, would be likely to affect a physician's decision to participate in Medicare or to otherwise accept assignment for a particular claim. This is because the amount that a provider is entitled to receive from the beneficiary for non-assigned claims is not affected by whether or not the VM is applicable to non-assigned claims. Additionally, to the extent our proposal to expand application of the VM to nonphysician eligible professionals is finalized, we would likewise apply the VM only to services billed on an assignment-related basis and not to non-assigned services. We invited comments on this proposed clarification.

The following is summary of the comments we received on this proposed clarification.

Comment: We received relatively few comments on this technical issue. For those that did comment, nearly all agreed with the proposed clarification and agreed it is important that beneficiary cost-sharing not be affected by the VM, and that the VM should be applied to the amount that Medicare pays to physicians. Some commenters requested a similar policy be applied to the payment adjustments for PQRS and EHR Meaningful Use. A commenter opposed the proposed clarification, encouraging CMS to support non-participating providers by applying the value modifier adjustment to non-assigned claims at the group practice level (TIN), and to evaluate alternative solutions to paying providers other than at the claim level.

Response: We appreciate receiving the comments that supported this technical clarification. However, we are unable to agree with the commenter that suggested an alternative approach to apply the VM to claims submitted by non-participating physicians. As explained above and in the proposal, the application of the VM to non-assigned claims by non-participating physicians would directly affect beneficiaries and not physicians, contrary to our intent. However, we further clarify that the VM will apply to all assigned claims, including those submitted by both participating and non-participating physicians, and nonphysician eligible professionals to the extent the VM is applied to them. Therefore, the VM will affect non-participating physicians to the extent that they submit assigned claims.

With regard to the comment that a similar policy for non-assigned claims be applied to the PQRS and EHR meaningful use adjustments, we believe

the comment is outside of the scope of the proposed rule, although we note that the VM is quite different from the PQRS and EHR-meaningful use adjustments, which apply to the Medicare allowed amount rather than the Medicare paid amount.

After considering the public comments, we are finalizing the proposed clarification to not apply the VM to non-assigned claims for non-participating physicians, and nonphysician eligible professionals to the extent the VM is applied to them.

f. Payment Adjustment Amount

Section 1848(p) of the Act does not specify the amount of payment that should be subject to the adjustment for the VM; however, section 1848(p)(4)(C) of the Act requires the VM be implemented in a budget neutral manner. Budget neutrality means that payments will increase for some groups and solo practitioners based on high performance and decrease for others based on low performance, but the aggregate expected amount of Medicare spending in any given year for physician and nonphysician eligible professional services paid under the Medicare PFS will not change as a result of application of the VM.

In the CY 2014 PFS final rule with comment period (78 FR 74770–74771), we adopted a policy to apply a maximum downward adjustment of –2.0 percent for the CY 2016 VM for those groups of physicians with 10 or more eligible professionals that are in Category 2 and for groups of physicians with 100 or more eligible professionals that are in Category 1 and are classified as low quality/high cost groups.

In the CY 2013 PFS final rule with comment period, we adopted a modest payment reduction of –1.0 percent for groups of physicians in Category 1 that elected quality tiering and were classified as low quality/high cost and for groups of physicians in Category 2 (77 FR 69323–24). Although we received comments suggesting that larger payment adjustments (both upward and downward) would be necessary to more strongly encourage quality improvements, we finalized our proposed adjustments as we believed they better aligned with our goal to gradually phase in the VM. However, we noted that as we gained experience with our VM methodologies we would likely consider ways to increase the amount of payment at risk, as suggested by some commenters (77 FR 69324).

We believe that we can increase the amount of payment at risk because we can reliably apply the VM to groups

with two or more eligible professionals and to solo practitioners in CY 2017 as discussed in section III.N.4.a of this final rule with comment period.

Therefore, we proposed to increase the downward adjustment under the VM by doubling the amount of payment at risk from –2.0 percent in CY 2016 to –4.0 percent in CY 2017 (79 FR 40505–40506). That is, for CY 2017, we proposed to apply a –4.0 percent VM to groups with two or more eligible professionals and solo practitioners that fall in Category 2. In addition, we proposed to increase the maximum downward adjustment under the quality-tiering methodology in CY 2017 to –4.0 percent for groups and solo practitioners classified as low quality/high cost and to set the adjustment to –2.0 percent for groups and solo practitioners classified as either low quality/average cost or average quality/high cost. However, as discussed in section III.N.4.c of this final rule with comment period, we proposed to hold solo practitioners and groups with two to nine eligible professionals that are in Category 1 harmless from any downward adjustments under the quality-tiering methodology in CY 2017. Consistent with our previous policy, we note that the estimated funds derived from the application of the downward adjustments to groups and solo practitioners in Category 1 and Category 2 would be available to all groups and solo practitioners eligible for VM upward payment adjustments. Accordingly, we also proposed to increase the maximum upward adjustment under the quality-tiering methodology in CY 2017 to +4.0x for groups and solo practitioners classified as high quality/low cost and to set the adjustment to +2.0x for groups and solo practitioners classified as either average quality/low cost or high quality/average cost (79 FR 40505). We also proposed to continue to provide an additional upward payment adjustment of +1.0x to groups and solo practitioners that care for high-risk beneficiaries (as evidenced by the average HCC risk score of the attributed beneficiary population). Lastly, we proposed to revise § 414.1270 and § 414.1275(c) and (d) to reflect the changes to the payment adjustments under the VM for the CY 2017 payment adjustment period. Table 87 shows the proposed quality-tiering payment adjustment amounts for CY 2017 (based on CY 2015 performance). We believe that the VM amount differentiates between cost and quality-tiers in a more meaningful way. We solicited comments on all of these proposals.

TABLE 87—PROPOSED CY 2017 VM PAYMENT ADJUSTMENT AMOUNTS

Cost/quality	Low quality	Average quality	High quality
Low Cost	+0.0%	*+2.0x	*+4.0x
Average Cost	–2.0%	+0.0%	*+2.0x
High Cost	–4.0%	–2.0%	+0.0%

* Groups and solo practitioners eligible for an additional +1.0x if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores.

The following is summary of the comments we received on all these proposals.

Comment: The majority of the comments were opposed to our proposals to increase the downward payment adjustments from CY 2016 to CY 2017 for groups and solo practitioners that fall in Category 2 and those that are low quality/high cost under the quality-tiering methodology to –4.0 percent. Commenters expressed their belief that the changes are aggressive. Several commenters indicated that CY 2017 will be the first year that many physicians and all nonphysician eligible professionals will be subject to the VM, and therefore, recommended maintaining the maximum downward payment adjustment at –2.0 percent for Category 2 and those that are low quality/high cost under the quality-tiering methodology. Commenters indicated that many of these groups and solo practitioners have not yet received their QRURs; therefore, it would be premature to raise the adjustment amount until all groups and solo practitioners have applicable cost and quality metrics and have had an opportunity to participate in the PQRS and VM programs. Commenters indicated that CMS should not increase the amount of payment at risk under quality-tiering and for Category 2 without providing an opportunity for both providers and CMS to understand the implications of the current policies as no group has had experience with the VM since it will be implemented in CY 2015. Other commenters suggested that groups and solo practitioners will have little time to fully understand their baseline performance under the VM. They suggested by delaying the increase of the maximum penalty, CMS would gain experience with applying the VM to a broader variety of groups, and that groups and solo practitioners would increase their understanding of the methodology used to calculate the VM and review their QRURs. Few commenters suggested that if CMS is concerned about PQRS reporting, then it should separate the amount at risk for not reporting under the PQRS (Category 2) from the amount at risk under

quality-tiering (Category 1) and that these adjustments should not be at the same level.

Other commenters noted that the cumulative impact of penalties for PQRS, EHR, and the VM would add up to a potential –9.0 percent adjustment to Medicare payments and expressed that this cumulative impact would be overly burdensome. One commenter indicated that the proposed changes would occur in a post-sequester payment environment where providers already experience a –2.0 percent reduction in Medicare payment. Some commenters indicated it was unfair to hold solo practitioners and groups with two to nine eligible professionals at –4.0 percent for the first year of the VM when groups with of 10 to 99 eligible professionals and groups with 100 or more eligible professionals EPs were at risk for only –2.0 percent and –1.0 percent respectively in their first year of the VM. These commenters suggested that we reduce their Category 2 downward payment adjustment for groups and solo practitioners during their first year in the VM.

By contrast, some supported all of our VM payment adjustment proposals and expressed their belief that a –4.0 percent downward adjustment and +4.0x upward adjustment factor was not sufficient to incentivize physicians to improve quality. A few of these commenters suggested that the amount at risk should eventually be approximately 10.0 percent and that CMS should create a plan in the final rule to continually increase the weight of the VM over time. One commenter noted that there is evidence in the private sector that higher incentives and penalties have a great impact on quality improvement.

Response: We acknowledge the commenters' concerns about doubling the amount of payment at risk from –2.0 percent in CY 2016 to –4.0 percent in CY 2017 under the VM. However, the literature documents a positive correlation between physician participation in quality improvement activities and the extent of the payment

adjustment.²² We agree with the commenters who suggested that smaller groups should be subject to a more gradual phase-in of the VM's application to them, consistent with the experience of the larger groups. We acknowledge that our proposal would have held solo practitioners and groups with two to nine eligible professionals in Category 2 at risk for up to a –4.0 percent payment adjustment for the first year of the VM when groups with of 10 to 99 eligible professionals and groups with 100 or more eligible professionals EPs were at risk for only –2.0 percent and –1.0 percent respectively in the first year that the VM applied to them. In light of these comments, we agree that a smaller increase in the maximum amount of payment at risk for groups with two to nine eligible professionals and solo practitioners would be consistent with our stated focus on gradual implementation and would allow small groups and solo practitioners to gain more experience with the QRURs and the application of the VM. Therefore, we are finalizing –2.0 percent as the maximum amount of payment at risk in CY 2017 for groups with two to nine eligible professionals and solo practitioners. Specifically, in CY 2017, for groups with two to nine eligible professionals and solo practitioners, we will apply a –2.0 percent VM to a group or solo practitioner that falls in Category 2. We note that, as discussed in section III.N.4.c of this final rule with comment period, we are finalizing our proposal to hold solo practitioners and groups with two to nine eligible professionals that are in Category 1 harmless from any downward adjustments under the quality-tiering methodology in CY 2017, if classified as low quality/high cost, low quality/average cost, or average quality/high cost. Additionally, for groups with two to nine eligible professionals and solo practitioners, we

²² Francois S. de Brantes & B. Guy D'Andrea. Physicians Respond to Pay-for-Performance Incentives: Larger Incentives Yield Greater Participation. *Am. J. of Managed Care*. 2009. 15,305–310. With regard to hospital participation, this correlation has been documented. Rachel M. Werner, et al. The Effect of Pay-For-Performance In Hospitals: Lessons for Quality Improvement. *Health Affairs*. 2011. 30,690–698.

are finalizing a policy to set the maximum upward adjustment under the quality-tiering methodology in CY 2017 to +2.0x if a group or solo practitioner is classified as high quality/low cost and set the adjustment to +1.0x if a group or solo practitioner is classified as either average quality/low cost or high quality/average cost. Table 88 shows the final quality-tiering payment adjustment amounts for CY 2017 (based on CY 2015 performance) for groups with two to nine eligible professionals and solo practitioners.

For groups with ten or more eligible professionals, we are finalizing the payment adjustments as proposed for CY 2017 (79 FR 40505–40506). As stated in the proposed rule (79 FR 40505), we believe that we can increase the amount of payment at risk because groups of this size will have had sufficient experience with the VM prior to the CY 2017 payment adjustment period. By CY 2017, groups with 10 or more eligible professionals will have had at least one year experience under the VM program. As stated in the CY 2014 PFS final rule with comment period (78 FR 74769), on September 16, 2013, we made available to all groups of 25 or more eligible professionals an annual QRUR based on 2012 data to help groups estimate their quality and cost composites. As discussed in section III.N.4.a. of this

final rule with comment period, in September 2014, we made available QRURs based on CY 2013 data to all groups of physicians and physicians who are solo practitioners. We believe that groups of 10 or more eligible professionals will have had adequate data to improve performance on the quality and cost measures that will be used to calculate the VM in CY 2017. As a result, we believe it is appropriate to increase the amount of payment at risk for groups with ten or more eligible professionals in CY 2017.

Consequently, for CY 2017, we will apply a –4.0 percent VM to groups with ten or more eligible professionals that fall in Category 2. In addition, we will set the maximum downward adjustment under the quality-tiering methodology in CY 2017 to –4.0 percent for groups with ten or more eligible professionals classified as low quality/high cost and set the adjustment to –2.0 percent for groups with ten or more eligible professionals classified as either low quality/average cost or average quality/high cost. We will also set the maximum upward adjustment under the quality-tiering methodology in CY 2017 to +4.0x for groups with ten or more eligible professionals classified as high quality/low cost and set the adjustment to +2.0x for groups with ten or more eligible professionals classified as either average

quality/low cost or high quality/average cost. Table 89 shows the final quality-tiering payment adjustment amounts for CY 2017 (based on CY 2015 performance) for groups with ten or more eligible professionals.

We are also finalizing our proposal to continue to provide an additional upward payment adjustment of +1.0x to groups with two or more eligible professionals and solo practitioners that care for high-risk beneficiaries (as evidenced by the average HCC risk score of the attributed beneficiary population). Lastly, we are finalizing the revisions at § 414.1270(c) and § 414.1275(c) and (d) to reflect the payment adjustments under the VM for the CY 2017 payment adjustment period. Tables 88 and 89 show the quality-tiering payment adjustment amounts for CY 2017 (based on CY 2015 performance). We believe that these final policies will alleviate commenters' concern that our proposals were too aggressive for smaller groups and solo practitioners that are new to the VM in CY 2017, while continuing the gradual phase-in of the VM for groups with ten or more eligible professionals with an emphasis on the importance of reporting under the PQRS program and improving the quality and efficiency of services provided to Medicare beneficiaries.

TABLE 88—FINAL CY 2017 VM PAYMENT ADJUSTMENT AMOUNTS FOR GROUPS WITH TWO TO NINE ELIGIBLE PROFESSIONALS AND SOLO PRACTITIONERS

Cost/quality	Low quality	Average quality	High quality
Low cost	+0.0%	*+1.0x	*+2.0x
Average cost	+0.0%	+0.0%	*+1.0x
High cost	+0.0%	+0.0%	+0.0%

* Groups and solo practitioners eligible for an additional +1.0x if reporting measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

TABLE 89—FINAL CY 2017 VM PAYMENT ADJUSTMENT AMOUNTS FOR GROUPS WITH TEN OR MORE ELIGIBLE PROFESSIONALS

Cost/quality	Low quality	Average quality	High quality
Low cost	+0.0%	*+2.0x	*+4.0x
Average cost	–2.0%	+0.0%	*+2.0x
High cost	–4.0%	–2.0%	+0.0%

* Groups eligible for an additional +1.0x if reporting measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

Consistent with the policy adopted in the CY 2013 PFS final rule with comment period (77 FR 69324 through 69325), the upward payment adjustment factor ("x" in Tables 88 and 89) will be determined after the performance period has ended based on the aggregate amount of downward payment adjustments. We noted in the proposed rule that the estimated funds derived

from the application of the downward adjustments to groups and solo practitioners in Category 1 and Category 2 would be available to all groups and solo practitioners eligible for VM upward payment adjustments (79 FR 40504).

In section III.N.4.d of the proposed rule (79 FR 40506), we discussed our proposal to apply the VM to physicians

in groups with two or more eligible professionals and to physicians who are solo practitioners that participate in the Shared Savings Program during the payment adjustment period beginning with the CY 2017 payment adjustment period. We noted in the CY 2015 PFS proposed rule that will have the final list of ACOs that will participate in the Shared Savings Program during the

payment adjustment period and their participant TINs during the late fall prior to the beginning of the payment adjustment period (for example, the late fall of CY 2016 prior to the CY 2017 payment adjustment period) (79 FR 40506). We also noted that this final list may not be available until after the beginning of the payment adjustment period. Therefore, we proposed to calculate preliminary payment adjustment factors (“x” in Table 87) prior to the beginning of the payment adjustment period, and subsequently finalize the payment adjustment factors after the final ACO participation list is completed. We note that the final payment adjustment factors may be updated depending on the outcome of the informal inquiry process described later at section III.N.4.i of this final rule with comment period.

We did not receive any comments on these proposals.

As discussed in section III.N.4.d of this final rule with comment period, we are finalizing a policy to use the performance period to determine which groups and solo practitioners participate in the Shared Savings Program for purposes of calculating their VM in CY 2017. Therefore, we are not finalizing our proposal to calculate preliminary payment adjustment factors (“x” in Tables 88 and 89) prior to the beginning of the payment adjustment period, and then recalculating the payment adjustment factors after the final ACO participation list is completed. However, we are finalizing our proposal that we may update the payment adjustment factors, depending on the outcome of the informal inquiry process described later at section III.N.4.i of this final rule with comment period.

g. Performance Period

In the CY 2014 PFS final rule with comment period (78 FR 74771 through 74772), we adopted a policy that performance on quality and cost measures in CY 2015 will be used to calculate the VM that is applied to items and services for which payment is made under the PFS during CY 2017. Accordingly, we added a new paragraph (c) to § 414.1215 to indicate that the performance period is CY 2015 for VM adjustments made in the CY 2017 payment adjustment period.

h. Quality Measures

In the CY 2014 PFS final rule with comment period (78 FR 74773), we aligned our policies for the VM for CY 2016 with the PQRS group reporting mechanisms available to groups in CY 2014 and the PQRS reporting mechanisms available to individual

eligible professionals in CY 2014, such that data that groups submit for quality reporting purposes through any of the PQRS group reporting mechanisms in CY 2014 and the data that individual eligible professionals submit through any of the individual PQRS reporting mechanisms in CY 2014 will be used for calculating the quality composite under the quality-tiering approach for the VM for CY 2016. Moreover, all of the quality measures for which groups and individual eligible professionals are eligible to report under the PQRS in CY 2014 would be used to calculate the VM for a group for CY 2016 to the extent the group or individual eligible professionals in the group submits data on such measure in accordance with our 50 percent threshold policy (78 FR 74768). We also noted that, in accordance with 42 CFR 414.1230, three additional quality measures (outcome measures) for groups subject to the VM will continue to be included in the quality measures used for the VM in CY 2016. These measures are: (1) A composite of rates of potentially preventable hospital admissions for heart failure, chronic obstructive pulmonary disease, and diabetes; (2) a composite rate of potentially preventable hospital admissions for dehydration, urinary tract infections, and bacterial pneumonia; and (3) rates of an all-cause hospital readmissions measure (77 FR 69315).

PQRS Reporting Mechanisms: It is important to continue to align the VM for CY 2017 with the requirements of the PQRS, because quality reporting is a necessary component of quality improvement. We also seek not to place an undue burden on eligible professionals to report such data. Accordingly, for purposes of the VM for CY 2017, we proposed to continue to include in the VM all of the PQRS GPRO reporting mechanisms available to groups for the PQRS reporting periods in CY 2015 and all of the PQRS reporting mechanisms available to individual eligible professionals for the PQRS reporting periods in CY 2015. These reporting mechanisms were described in Tables 21 through 49 of the proposed rule (79 FR 40404).

PQRS Quality Measures: We proposed to continue to use all of the quality measures that are available to be reported under these various PQRS reporting mechanisms to calculate a group or solo practitioner’s VM in CY 2017 to the extent that a group (or individual eligible professionals in the group, in the case of the “50 percent option”) or solo practitioner submits data on these measures. These PQRS quality measures were described in

Tables 21 through 49 of the proposed rule (79 FR 40404).

We proposed that groups with two or more eligible professionals would be able to elect to include the patient experience of care measures collected through the PQRS CAHPS survey for CY 2015 in their VM for CY 2017 (79 FR 40506). We also proposed to continue to include the three outcome measures in § 414.1230 in the quality measures used for the VM in CY 2017. For groups that are assessed under the “50 percent option” for the CY 2017 VM, we proposed to calculate the group’s performance rate for each measure reported by at least one eligible professional in the group by combining the weighted average of the performance rates of those eligible professionals reporting the measure. We also proposed for groups that are assessed under the “50 percent option” for the CY 2017 VM to classify a group’s quality composite score as “average” under the quality-tiering methodology, if all of the eligible professionals in the group satisfactorily participate in a PQRS qualified clinical data registry in CY 2015 and we are unable to receive quality performance data for those eligible professionals. We wish to clarify that in this proposal, the phrase “all of the eligible professionals in the group” refers to the at least 50 percent of eligible professionals in the group who report as individuals under PQRS. In other words, we proposed for groups that are assessed under the “50 percent option” for the CY 2017 VM, where all of the eligible professionals in the group who report as individuals under PQRS do so by satisfactorily participating in a PQRS qualified clinical data registry in CY 2015, and we are unable to receive quality performance data for those eligible professionals, then we would classify the group’s quality composite score as “average” under the quality-tiering methodology. If some EPs in the group report data using a qualified clinical data registry and we are unable to obtain the data, but other EPs in the group report data using the other PQRS reporting mechanisms for individuals, we would calculate the group’s score based on the reported performance data that we obtain through those other mechanisms (79 FR 40507).

Although we finalized policies in the CY 2014 final rule with comment period that would allow groups assessed under the “50 percent option” to have data reported through a PQRS qualified clinical data registry in CY 2014 used for the purposes of their CY 2016 VM to the extent performance data are available, we noted that we did not directly address the issue of how we

would compute the national benchmarks for these measures. Under § 414.1250, benchmarks for the quality of care measures for the VM are the national mean performance rate for a measure during the year prior to the performance period. In the CY 2013 PFS final rule (77 FR 69322), we finalized a policy that if a measure is new to the PQRS, we will be unable to calculate a benchmark and performance on that measure and will therefore not be included in the quality composite. Consistent with these existing policies, we proposed to not include in the VM quality composite those measures reported through a PQRS qualified clinical data registry that are new to PQRS (in other words, measures that were not previously reported in PQRS) (79 FR 40507). This policy would apply beginning with the measures reported through a PQRS qualified clinical data registry in the CY 2014 performance period for the CY 2016 payment adjustment period. We welcomed public comment on this proposal.

We noted that the PQRS administrative claims option described in § 414.1230, is no longer available through PQRS (79 FR 40507). However, we are clarifying that the three claims-based outcome measures described in § 414.1230, are still used in calculating the quality composite for purposes of the VM. We proposed to clarify that we calculate benchmarks for those outcome measures described in § 414.1230 using the national mean for a measure's performance rate during the year prior to the performance period in accordance with our regulation at § 414.1250(b) (79 FR 40507). We welcomed public comment on this proposal.

The following is summary of the comments we received on these proposals.

Comment: Several commenters supported the alignment of VM with PQRS requirements. Other commenters, however, raised concerns about the lack of applicable quality measures for multiple specialties and nonphysician eligible professionals, which they believe could result in an automatic downward payment adjustment for professionals who are unable to report. Several commenters also suggested CMS should include measures in the VM only after physicians had reported on the measures under PQRS for at least a year. Several commenters supported our proposal to continue our existing VM benchmarking policy for measures that are new to PQRS or reported via a Qualified Clinical Data Registry (QCDR). Several commenters supported our proposal to allow optional reporting of patient experience of care measures for

groups of two or more physicians. However several commenters urged us to consider additional patient experience measures that are relevant to beneficiaries using specific Medicare benefits. One commenter suggested that CAHPS data should be collected throughout the year, allowing providers to prioritize and monitor the effectiveness of improvement efforts, especially as patient experience of care data will be incorporated into the VM in CY 2017. One commenter suggested that the patient experience of care measures should be optional for quality tiering for the CY 2017 VM, as the 2013 GPRO web participants are still awaiting the results of the survey administration. A number of commenters stated that CMS should not make patient experience measures a required component of the VM in the future.

Response: PQRS measures are highly reliable measures for understanding the health and functional status of beneficiaries after treatment by a participating group or solo practitioner.²³ In previous rulemakings we have committed to expanding the specialty measures available in PQRS in order to more accurately measure the performance on quality of care furnished by specialists and we reaffirm our commitment to using measures of performance across specialties that are reliable and valid for the VM program (77 FR 69315; 78 FR 74773). Moreover, we believe group reporting can ameliorate the commenters' concerns that the current set of PQRS measures does not capture all of the clinical care that some specialists and sub-specialists furnish. We also continue to believe that alignment with the PQRS program is an important goal for the VM, because it minimizes burden on providers and encourages widespread participation in quality reporting.

As we stated in section III.N.4.a of this final rule with comment period, where a group or solo practitioner falls in Category 1 under the VM (that is, meets the criteria to avoid the CY 2017 PQRS payment adjustment), but the group or solo practitioner does not have at least 20 cases for each PQRS measure on which it reports as required for inclusion in the quality composite of the VM, the group or solo practitioner's quality composite score would be based on the three claims-based outcome measures described at § 414.1230, provided that the group or solo practitioner has at least 20 cases for at least one of the claims-based outcome

measures. As discussed in section III.N.4.h of this final rule with comment period, eligible professionals and groups concerned about the lack of specialty measures to meet PQRS reporting requirements should note that PQRS has a Measure Applicability Validation (MAV) process. MAV determines PQRS incentive eligibility for eligible professionals and groups reporting less than nine measures across three domains or nine or more across less than three domains. We recommend that commenters refer to the Measure Application Validation (MAV) Process to alleviate concerns that lack of applicable measures would result in an automatic downward adjustment under the VM. http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2014_PQRS_Claims_MeasureApplicabilityValidation_12132013.zip. Also, please refer to section III.K.2 of this final rule with comment period for the final 2017 policies for MAV and the criteria for satisfactory reporting for the 2017 PQRS payment adjustment.

With regard to the commenters' suggestion that the VM should include only measures on which physicians have reported under PQRS for at least one year, we note that we are maintaining the policy set forth in § 414.1250 that benchmarks for the quality of care measures are the national mean of a measure's performance rate during the year prior to the performance period. Measures reported through a PQRS qualified clinical data registry that are new to PQRS would not be included in the quality composite for the VM because we would not be able to calculate benchmarks for them. We acknowledge the interest in ensuring that physicians report on measures for at least one year before they are included in the VM. Our current policy achieves that end by precluding the use of measures for which no benchmarking data is available. We acknowledge the comments suggesting that CMS expand the data collected on the patient experience of care (CAHPS) measures and note that we seek to align with the PQRS program in order to minimize reporting burden and align incentives across CMS incentive payment programs. We will consider these suggestions for any future refinements to the patient experience measures included in the PQRS program and the VM. CMS will provide survey results and post benchmarks for the patient experience of care measures; this data as well as the survey questions that can be accessed on the CMS Web site can be

²³ Mathematica Policy Research, "Experience Report for the Performance Year 2012 Quality and Resource Use Reports." (January 8, 2014).

utilized to prioritize performance improvement efforts. We also acknowledge the commenters' concerns with expansion of mandatory CAHPS inclusion in the VM and note that we would propose any such policy change through future notice and comment rulemaking.

After consideration of the comments, we are finalizing our proposal to use all of the quality measures that are available to be reported under these various PQRS reporting mechanisms to calculate a group or solo practitioner's VM in CY 2017, to the extent that a group (or individual eligible professionals in the group, in the case of the "50 percent option") or solo practitioner submits data on these measures. We are finalizing our policy that groups with two or more eligible professionals can elect to include the patient experience of care measures collected through the PQRS CAHPS survey for CY 2015 in their VM for CY 2017. We are finalizing our policy to continue to include the three outcome measures in § 414.1230 in the quality measures used for the VM in CY 2017. We are finalizing our policy that for groups that are assessed under the "50 percent option" for the CY 2017 VM, we will calculate the group's performance rate for each measure reported by at least one eligible professional in the group by combining the weighted average of the performance rates of those eligible professionals reporting the measure.

We are finalizing our policy at § 414.1270(c)(4) that, for groups that are assessed under the "50 percent option" for the CY 2017 VM, where all of the eligible professionals in the group who report as individuals under PQRS do so by satisfactorily participating in a PQRS qualified clinical data registry in CY 2015, and we are unable to receive quality performance data for those eligible professionals, then we will classify the group's quality composite score as "average" under the quality-tiering methodology. Because this is the same policy as for the CY 2016 payment adjustment period, we are also making a conforming revision to § 414.1270(b)(4).

We are finalizing a policy that, for groups that are assessed under the "50 percent option" where some EPs in the group report data using a qualified clinical data registry and we are unable to obtain the data, but other EPs in the group report data using the other PQRS reporting mechanisms for individuals, then we will calculate the group's score based on the reported performance data that we obtain through those other PQRS reporting mechanisms. We are

finalizing a policy that, beginning with the CY 2014 performance period, measures reported through a PQRS qualified clinical data registry that are new to PQRS will not be included in the quality composite for the VM until such time as we have historical data to calculate benchmarks for them. Once we have historical data from measures submitted via QCDRs, the benchmark for quality of care measures will be the national mean for the measure's performance rate during the year prior to the performance period (§ 414.1250). We are finalizing our proposed clarification that we calculate benchmarks for the outcome measures described in § 414.1230 using the national mean for a measure's performance rate during the year prior to the performance period in accordance with our regulation at § 414.1250(b). Although we did not include proposed regulation text for this proposed clarification of our policy, we are finalizing revisions to regulation text at § 414.1250(b) to reflect this final policy.

Quality Measures for the Shared Savings Program: Starting with the CY 2017 payment adjustment period, as described in section III.M. of this final rule with comment period, we proposed to apply the value modifier to groups and solo practitioners participating in ACOs under the Shared Savings Program. To do so, we proposed quality measures and benchmarks for use with these groups and solo practitioners and solicited public comment on these proposals. We describe these proposals more fully below.

With regard to quality measures, we noted that there is substantial overlap between those used to evaluate the ACOs under the Shared Savings Program and those used in the PQRS program and for the value modifier payment adjustment. For the CY 2017 payment adjustment period and subsequent payment adjustment periods, to determine a quality composite for the VM for groups and solo practitioners who participate in an ACO under the Shared Savings Program, we proposed to use the quality measures that are identical for the two programs. Specifically, for the CY 2017 payment adjustment period, we proposed to use the PQRS GPRO Web Interface measures and the outcome measure described at § 414.1230(c) to determine a quality composite for groups and solo practitioners who participate in an ACO under the Shared Savings Program. Because the ACO GPRO Web Interface measures and PQRS GPRO Web Interface measures will be the same in CY 2015, we proposed to use the GPRO Web Interface measures reported by

ACOs in determining the quality composite for groups and solo practitioners participating in ACOs under the Shared Savings Program in CY 2017 (79 FR 40507). Utilizing these GPRO Web Interface measures in this regard further encourages successful quality reporting for Shared Savings Program ACOs. Additionally, we stated our belief that the all-cause hospital readmissions measure as calculated for ACOs under the Shared Savings Program is equivalent to the all-cause hospital readmissions measure we have adopted for the VM at § 414.1230(c), and therefore, proposed use of that measure as calculated for ACOs in the Shared Savings Program for inclusion in the VM for the CY 2017 payment adjustment period (79 FR 40507). We note that the outcome measures described at § 414.1230(a) and § 414.1230(b) are not currently calculated for ACOs in the Shared Savings Program. These measures are: (1) A composite of rates of potentially preventable hospital admissions for heart failure, chronic obstructive pulmonary disease, and diabetes; and (2) a composite rate of potentially preventable hospital admissions for dehydration, urinary tract infections, and bacterial pneumonia. Because we have no experience with these measures in the Shared Savings Program, at this time, we did not propose to include these measures for groups and solo practitioners who participate in ACOs under that program. We proposed to modify the regulations at § 412.1210 accordingly.

The following is summary of the comments we received on these proposals.

Comment: The majority of commenters opposed the proposals for two reasons. First, these commenters expressed their belief that the ACO would be required to report measures twice or report additional measures. Second, these commenters suggested that aligning the measures used in the Shared Savings Program and those in the VM program could lead to ACOs scoring well in one program while performing poorly in the other. Commenters believe that the VM and Shared Savings Program use different performance benchmarks and different approaches for determining good versus bad performance.

A few medical societies supported the proposals, recognizing CMS's intent to align the measures and quality improvement goals of the Shared Savings Program and VM program. Several commenters suggested allowing groups that are new to GPRO Web Interface reporting to have at least one

year to report measures before they are measured for performance. A few commenters recommended aligning the Shared Savings and the VM programs by removing the three claims-based outcome measures from the VM.

Response: We disagree with the commenters' suggestion that utilizing GPRO Web Interface measures to calculate Shared Savings Program ACO's quality composites would cause them additional reporting burden, because the ACO GPRO Web-Interface measures and PQRS GPRO Web-Interface measures are the same. We believe, therefore, that utilizing the GPRO web interface measures for Shared Savings Program ACO quality composite calculation under the VM will further encourage successful quality reporting for ACOs in the Shared Savings Program and will not add burdensome reporting requirements. ACOs in the Shared Savings Program would not have to report measures twice for purposes of the VM. Moreover, the use of the GPRO Web Interface measures fosters alignment among the various CMS quality reporting programs. With regard to commenters' suggestion that Shared Savings Program ACO participants might fare well on measures reported under the Shared Savings Program and poorly under the VM program, we do not believe this situation is likely to occur, because within the Shared Savings Program, ACOs will be measured against national benchmarks that are calculated using Medicare fee-for-service data. The VM program also develops benchmarks using all available Medicare fee-for-service data. Although the benchmarking methodology differs in that the VM uses a national weighted mean and the Shared Savings Program use a decile distribution for measuring performance, we believe using the same data source enables a fair comparison for all groups and solo practitioners subject to the value modifier.

Further, we believe it is appropriate to use the Shared Savings Program ACOs' all-cause readmission measure for calculating the VM for the CY 2017 payment adjustment period. As we stated in the proposed rule, we believe that the Shared Savings Program ACO all-cause readmission measure is equivalent to the all-cause hospital readmission measure adopted for the VM. The use of this measure will not impose any additional reporting burden on Shared Savings Program ACOs (79 FR 40508).

After considering the public comments, we are finalizing a policy to use the ACO Group Practice Reporting Option (GRPO) Web Interface measures

and the Shared Savings Program ACO all-cause readmission measure to calculate a quality composite score for groups and solo practitioners who participate in an ACO under the Shared Savings Program.

To determine the standardized scores for these quality measures for use with those participating in ACOs under the Shared Savings Program, we proposed to apply the benchmark policy for quality measures for the VM as described under § 414.1250. Under this policy, the VM benchmarks are the national mean for a measure's performance rate based on data from one year prior to the performance period. We believe these are the appropriate benchmarks to use when determining the value modifier payment adjustment because they are the same benchmarks used to determine the value modifier payment adjustment for other groups and solo practitioners and they are similar to the benchmarks used under the Shared Savings Program. As stated above, within the Shared Savings Program, ACOs will be measured against national benchmarks that are calculated using Medicare fee-for-service data and the VM program also develops benchmarks using all available Medicare fee-for-service data. We believe that use of the VM benchmarks creates a reasonable comparison among groups and solo practitioners and it is appropriate to evaluate those that participate in Shared Savings Program ACOs on the same basis as those that do not participate in the Shared Savings Program for the purpose of the value modifier. We believe that the VM benchmarks are appropriate because they include all PQRS data available (77 FR 69322), including quality data used for the Shared Savings Program. We stated that, while the Shared Savings Program develops benchmarks using all available Medicare fee-for-service data, we do not believe it is appropriate to use benchmarks from the Shared Savings Program to determine standardized scores for the quality composite of the value modifier payment adjustment. We do not think this enables a fair comparison among groups and solo practitioners subject to the value modifier because the Shared Savings Program benchmarks use gradients by decile (including the median) of national performance based on data two years prior to the performance period (78 FR 74759 through 74760).

The following is summary of the comments we received on these proposals.

Comment: A number of commenters opposed the proposal for the following

reasons: The belief that a difference in performance benchmarks for the VM and Shared Savings Program could cause ACOs to score well in one program and perform poorly in the other; and the belief that the application of the VM benchmarking policy to the quality measures used by ACOs under the Shared Savings Program could introduce potential bias into the broader VM program. One commenter supported our proposal, noting that alignment of quality measures for the VM and Shared Savings Program would strengthen the benchmarks by establishing a larger pool of providers with comparable measures.

Response: We appreciated the comments received. As stated above, with regard to the suggestion that Shared Savings Program ACO participants might fare well on measures reported under the Shared Savings Program and poorly under the VM program, we do not believe this situation is likely to occur, because the GPRO Web Interface measures used for the Shared Savings Program ACOs and the VM are the same and benchmarks used for performance measurement on use the same data source (fee-for-service Medicare data). We also do not believe that introduction of SSP ACO data into the benchmarks would create a bias. We utilize national data for benchmarking, and we agree with the commenter who stated that this will strengthen the benchmarks by expanding the pool of participants. After consideration of the public comments received, we are finalizing the proposal to apply the benchmark policy for quality measures for the VM as described under § 414.1250 to determine the standardized score for quality measures for groups and solo practitioners participating in ACOs under the Shared Savings Program.

All-Cause Hospital Readmissions Measure: We finalized the inclusion of the all-cause hospital readmissions measure described at § 414.1230(c) in the CY 2013 PFS final rule with comment (77 FR 69285). We subsequently investigated the reliability of this measure. We also have an existing policy at § 414.1265, that a claims-based cost or quality measure must have a minimum of 20 cases, to be included in a composite score calculation. Furthermore, according to § 414.1265(a), if a group has fewer than 20 cases for a measure in a performance period, that measure is excluded from its domain and the remaining measures in the domain are given equal weight.

Based on 2012 data, we found that the average reliability for the all-cause hospital readmissions measure was

below 0.4 when we examined groups with fewer than 200 cases but exceeded 0.4 for groups with 200 or more cases. Although we do not believe there is a universal consensus concerning a minimum reliability threshold, reliability scores in the 0.4 to 0.7 range are often considered moderate, and scores greater than 0.7 are considered high. In general, we found that the groups with at least 10 eligible professionals were more likely to have 200 or more cases as compared to groups with fewer eligible professionals. Thirty percent of groups with 10 or more eligible professionals had 200 or more cases, as compared to 3 percent of groups with 1–9 eligible professionals. We found that the average reliability exceeded 0.4 for groups of all sizes (1 or more eligible professionals), with 200 or more cases.

After examining the reliability of the all-cause hospital readmissions measure data for 2012 across all group sizes and considering its impacts on the cost composite of the VM as discussed below, we proposed to change the reliability policy (minimum number of cases) with respect to this measure. Specifically, beginning with the CY 2017 payment adjustment period, we proposed to change the reliability policy (minimum number of cases) with respect to the all-cause hospital readmissions measure as described in § 414.1230(c) from a minimum of 20 cases to a minimum of 200 cases for this measure to be included in the quality composite for the VM. For this measure only, we proposed to exclude the measure from the quality domain for a group or solo practitioner if the group or solo practitioner has fewer than 200 cases for the measure during the relevant performance period. In implementing this proposal, we noted that we would only apply it to the all-cause hospital readmissions measure as it is calculated for groups or solo practitioners who are not part of a Shared Savings Program ACO. In instances where we are including Shared Savings Program data for groups or solo practitioners who are part of a Shared Savings Program ACO, we would include their all-cause hospital readmissions measure as it is calculated for the Shared Savings Program. This approach to implementing this proposal is appropriate because the Shared Savings Program has taken into consideration the size of its groups in finalizing inclusion of this measure, and we value consistency with the Shared Savings Program's reporting requirements for its participants, to the extent it is practicable. We would

continue to include the measure in the VM quality domain for groups or solo practitioners who have 200 or more cases. We proposed to modify § 414.1265 to reflect this proposal. We welcomed comments on this proposal.

We noted that, if we were to revise the minimum case size for the all-cause hospital readmissions measure for the quality composite of the VM, poor performance on controlling readmissions would continue to have an effect on the VM for groups with between 20 and 199 cases through the cost composite of the VM. The Medicare Spending per Beneficiary (MSPB) measure, as finalized in the CY 2014 PFS final rule (78 FR 74775–74780), is a measure of all Medicare Part A and Part B payments during an episode spanning from 3 days prior to an index hospital admission through 30 days post-discharge with certain exclusions. Since all Part A and Part B spending is included in the 30 day post-discharge window, Medicare Part A payments for a readmission that are included in an MSPB episode will increase the MSPB amount relative to an MSPB episode without a readmission in the 30-day post-discharge window. Additionally, the cost of readmissions is incorporated as part of the 5 total per capita cost measures that comprise the remainder of the cost composite of the VM. The 5 total per capita cost measures are annual measures that include the costs of all Part A and Part B spending during the year, including the costs of readmissions. Therefore, readmission costs will have the effect of increasing total per capita cost spending for the groups attributed these patients' costs. As a result, poor performance on controlling readmissions already will have an adverse effect on an attributed group's cost composite of the VM, even if poor performance on the all-cause hospital readmissions measure would no longer be reflected in certain groups' or solo practitioners' quality composite of the VM due to having fewer than 200 all-cause hospital readmission cases. Even for those groups for which the all-cause hospital readmissions measure would be excluded from the quality composite calculations, groups would continue to have incentive to control readmissions, since doing so would reduce readmission costs, thereby improving performance on the payment-standardized, risk-adjusted cost measures used for the cost composite of the VM.

The following is summary of the comments we received on this proposal.

Comment: We received few comments on this proposal. Some commenters supported the inclusion of the all-cause

readmission measure. One commenter supported the proposed change in the reliability policy for the hospital all-cause readmission measure, stating that this will provide valid and reliable estimates for hospital admissions to each group. Several commenters supported the need for reliable measures; however, one commenter expressed concern that even with an increased case minimum, the all-cause readmission measure was still not appropriate for physician accountability because the readmission costs are already included in the total per capita costs, the measure was not specified for group level measurement, and the measure was not supported by the Measures Application Partnership (MAP). This commenter stated that the all-cause readmission measure does not add value to the VM, further suggesting that if CMS chooses to keep the measure, then it should be adjusted for clinical and socioeconomic factors. Another commenter recommended CMS undertake an analysis to ensure this change would not result in disproportionate penalties for certain groups (such as surgeons) prior to finalizing this proposal.

One commenter stated that this measure is not appropriate for physician practices because 2012 data indicates that the measure could not meet a 0.4 percent reliability threshold at a 20-case minimum. This commenter also questioned the justification for including a measure that will be applicable only to 30 percent of groups with 10 or more practitioners and three percent of smaller groups, even when the proposed minimum 200 case threshold is utilized.

Response: We disagree with the commenters' assessment of the reliability of the all-cause hospital readmission measure, which quantifies the unplanned readmissions for any cause within 30 days from the date of discharge of an index admission. Our analysis of this measure based on 2012 data found that the average reliability exceeded 0.4 for groups with 200 or more cases included all group sizes (1 or more eligible professionals). We are committed to monitoring this measure, as well as others to ensure that the minimum patient panel size is sufficient to meet the reliability standard for the VM program. With regard to concern that readmission costs are included in other spending measures, we disagree that this fact makes the all-cause hospital readmissions measure inappropriate for inclusion in the VM. The all-cause hospital readmissions measure is a measure of readmission rates, not of costs and we believe that

readmission reduction is an important goal that we can emphasize through the VM. We note that the measure's direction was supported by the MAP and also that the has been specified for groups. The group specifications may be found at: <http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO-8.pdf>

With regard to commenters' concerns related to the issue of socioeconomic status adjustment, we continue to monitor activities at the National Quality Forum (NQF), such as the July 23, 2014 decision by the NQF Board in which the Board approved a trial period to test the impact of sociodemographic factor risk adjustment of performance measures (available at http://www.qualityforum.org/Press_Release/2014/NQF_Board_Approves_Trial_Risk_Adjustment.aspx). While we continue to evaluate the appropriateness of applying different standards for the outcomes of patients of low socioeconomic status and the potential for a socioeconomic status adjustment to mask potential disparities or minimize incentives to improve the outcomes of economically disadvantaged populations, we would take any future decision by the NQF on this issue into consideration for any potential future refinements to this or any measure included in the VM.

After consideration of the comments, we are finalizing the policy, beginning with the CY 2017 payment adjustment period, to increase the case minimum from 20 cases to 200 cases for the all-cause hospital readmissions measure as described in § 414.1230(c) to be included in the quality composite for the VM as proposed. Therefore, we are finalizing the proposal to exclude the measure from the quality domain for a group or solo practitioner if the group or solo practitioner has fewer than 200 cases for the measure during the relevant performance period and all remaining measures in the domain will be given equal weight. We are codifying this change with a revision to the regulation at § 414.1265.

i. Expansion of the Informal Inquiry Process To Allow Corrections for the Value-Based Payment Modifier

Section 1848(p)(10) of the Act provides that there shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following:

- The establishment of the VM;
- The evaluation of the quality of care composite, including the establishment of appropriate measures of the quality of care;

- The evaluation of the cost composite, including the establishment of appropriate measures of costs;

- The dates of implementation of the VM;

- The specification of the initial performance period and any other performance period;

- The application of the VM; and

- The determination of costs.

These statutory requirements regarding limitations of review are reflected in § 414.1280. Despite the preclusion of administrative and judicial review, we previously indicated in the CY 2013 PFS final rule with comment period (77 FR 69326) that we believed an informal review mechanism is appropriate for groups of physicians to review and to identify any possible errors prior to application of the VM, and we established an informal inquiry process at § 414.1285. We stated that we intend to disseminate reports containing CY 2013 data in the fall of 2014 to groups of physicians subject to the VM in 2015 and that we will make a help desk available to address questions related to the reports.

We stated it would be appropriate to align with PQRS to consider requests for informal review of whether a group or solo practitioner successfully reported under the PQRS program and requests for reconsideration of PQRS data as described in section III.K, as well as to expand our current informal inquiry process to accept requests from groups and solo practitioners to review and correct certain other errors related to the VM, such as errors made by CMS in assessing the eligibility of a group or solo practitioner for the value modifier based on participation in a Shared Savings Program ACO, the Pioneer ACO Model, the CPC Initiative, or other similar Innovation Center models or CMS initiatives; computing standardized scores; computing domain scores; computing composite scores; or computing outcome or cost measures. We are working to develop and operationalize the necessary infrastructure to support such a corrections process, but at this time, we do not believe we would be able to implement the process until 2016 at the earliest.

Therefore, for the CY 2015 payment adjustment period, to align with PQRS, we proposed to expand the informal inquiry process at § 414.1285 to establish an initial corrections process that would allow for some limited corrections to be made (79 FR 40509). Specifically, under this initial corrections process, for the CY 2015 payment adjustment period, we proposed to establish a deadline of

January 31, 2015 for a group to request correction of a perceived error made by CMS in the determination of its CY 2015 VM payment adjustment. Alternatively, we solicited comment on a deadline of no later than the end of February 2015 to align with the PQRS informal review process. We would then make a determination regarding the request. At this time, we do not anticipate it would be operationally feasible for us to fully evaluate errors with regard to quality measure data and accept data as described above under section III.K. for the CY 2015 payment adjustment period, and thus we proposed to classify a TIN as "average quality" in the event we determine that we have made an error in the calculation of quality composite. We proposed to recompute a TIN's cost composite in the event we determine that we have made an error in its calculation. We proposed to adjust a TIN's quality-tier if we make corrections to a TIN's quality and/or cost composites as a result of this initial corrections process. We noted that there would be no administrative or judicial review of the determinations resulting from this expanded informal inquiry process under section 1848(p)(10) of the Act.

Starting with the CY 2016 payment adjustment period (which has a performance period of CY 2014), we proposed to continue the expanded informal inquiry process at § 414.1285 as described above. However, in anticipation of having the necessary operational infrastructure to support the reconsideration of quality measure data, we proposed to establish a 30-day period that would start after the release of the QRURs for the applicable performance period for a group or solo practitioner to request correction of a perceived error made by CMS in the determination of the group or solo practitioner's VM for that payment adjustment period. These QRURs contain performance information on the quality and cost measures used to calculate the quality and cost composites of the VM and will show how all TINs would fare under the policies established for the VM for the CY 2015 payment adjustment period. Similar to our proposal for the initial corrections process in CY 2015, we would then make a determination regarding the requests received. Since we anticipate it would be operationally feasible for us to fully evaluate errors with regard to quality measure data at that point, and accept data, consistent with PQRS policies, as described above under section III.K. for the CY 2016 payment adjustment period, we

proposed to recompute a TIN's quality composite and/or cost composite in the event we determine that we have made an error in the calculation. We noted that if the operational infrastructure is not available to allow this recomputation, we proposed to continue the approach of the initial corrections process to classify a TIN as "average quality" in the event we determine that we have made an error in the calculation of the quality composite. We proposed to adjust a TIN's quality-tier if we make a correction to a TIN's quality and/or cost composites as a result of this corrections process.

We welcomed comment on these proposals.

The following is summary of the comments we received on both the initial corrections process in the CY 2015 payment adjustment period and the corrections process we proposed beginning with the CY 2016 payment adjustment period.

Comment: Commenters supported implementing an expanded informal inquiry process to allow for corrections to the VM. However, almost all commenters requested later deadlines for submission of VM corrections. Specifically:

- For 2015, most commenters supported establishing a deadline of no later than the end of February 2015, rather than January 31, to align with the PQRS informal review process.

- For subsequent years, most commenters requested a longer period of 60 to 90 days (rather than 30 days) that would start after the release of the QRURs for the applicable performance period for a group or individual to request a correction of a perceived error related to the VM calculation.

In addition, some commenters objected to the proposal for 2015 to classify a TIN as "average quality" in the event we determined that we have made an error in the calculation of the quality composite. These commenters believe it would be inappropriate to deem a group "average quality" simply because CMS does not have the capacity to correct its own errors, especially if an "average quality" rating could potentially lead to penalties or lost incentive payments. Some commenters suggested that we consider requests for providers to resubmit their quality data. Other commenters asked that we provide additional clarification regarding what situations will be considered in the informal review process.

Response: We are persuaded by commenters who request that we establish later deadlines for the VM informal review process so that such

deadlines are consistent with those of the PQRS informal review process. We agree with these comments since data reported under PQRS is an important component of the VM and that corrections to PQRS measure rates could affect the calculation of the VM payment adjustment amount. Therefore, for the CY 2015 payment adjustment period, the deadline for submission of a request for VM informal review will be the end of February, 2015. Likewise, for subsequent payment adjustment years, we are persuaded by commenters that requested a longer period beyond 30 days, which would start after the release of the QRURs for the applicable performance period, for a group or individual to request a correction of a perceived error related to the VM calculation. However, we believe that 60 days, not 90 days, would be a sufficient amount of time for providers to access their QRUR reports, review the information, which includes the VM payment adjustment amount that will apply for the subsequent payment adjustment year and make a decision whether or not to submit a VM correction request. Establishing a 60-day deadline enables us to make corrections prior to, or relatively soon after, the start of the applicable payment adjustment year. This helps reduce the number of claims that would need to subsequently be reprocessed during the applicable payment adjustment year.

Finally, as we discussed in the proposal and above, it is not operationally feasible to fully evaluate errors with regard to quality measure data and accept data as described above under section III.K. for the CY 2015 payment adjustment period. Therefore, to minimize the impact on providers, we will classify a TIN as "average quality" in the event that we determine that we have made an error in the calculation of the quality composite. However, we understand the point made by a few commenters about this policy. It is possible that an "average quality" rating for the CY 2015 payment adjustment period could potentially result in a higher or lower VM payment adjustment amount for an individual TIN than if the quality composite were recalculated. Therefore, we are working to develop the operational infrastructure to allow us to re-compute a TIN's quality composite and accept data, consistent with PQRS quality data resubmission policies, as described above under section III.K. for the CY 2016 payment adjustment period in the event we determine that we have made an error in the calculation.

After consideration of the public comments received:

- For the CY 2015 payment adjustment period, we are: (1) Finalizing a February 28, 2015, deadline for a group to request correction of a perceived error made by CMS in the determination of its VM, and (2) finalizing a policy to classify a TIN as "average quality" in the event we determined that we have made an error in the calculation of the quality composite.

- Beginning with the CY 2016 payment adjustment period, (1) we are finalizing a deadline of 60 days that would start after the release of the QRURs for the applicable performance period for a group or solo practitioner to request a correction of a perceived error related to the VM calculation, and (2) we will take steps to establish a process for accepting requests from providers to correct certain errors made by CMS or a third-party vendor (for example, registry). We intend to design this process as a means to re-compute a TIN's quality composite and/or cost composite in the event we determine that we initially made an erroneous calculation. We note that if the operational infrastructure is not available to allow this re-computation, we will continue the approach for the CY 2015 payment adjustment period to classify a TIN as "average quality" in the event we determine that we have made an error in the calculation of the quality composite.

For both the CY 2015 payment adjustment period and future adjustment periods, we will adjust a TIN's quality-tier if we make a correction to a TIN's quality and/or cost composites as a result of this corrections process. We will provide additional operational details as necessary in sub-regulatory guidance.

We further note that there is no administrative or judicial review of the determinations resulting from this expanded informal inquiry process under section 1848(p)(10) of the Act.

j. Potential Methods To Address NQF Concerns Regarding the Total Per Capita Cost Measures

In the CY 2013 PFS final rule with comment period (77 FR 69322), we established a policy to create a cost composite for each group subject to the VM that includes five payment-standardized and risk-adjusted annual per capita cost measures. To calculate each group's per capita cost measures, we first attribute beneficiaries to the group. We attribute beneficiaries using a two-step attribution methodology that is based on the assignment methodology used for the Shared Savings Program and the PQRS GPRO and that focuses on

the delivery of primary care services (77 FR 69320) by both primary care physicians and specialists.

In the CY 2014 PFS final rule with comment period (78 FR 74780), we finalized inclusion of the Medicare Spending Per Beneficiary (MSPB) measure as proposed in the cost composite beginning with the CY 2016 VM, with a CY 2014 performance period. As we proposed, we are using the MSPB amount as the measure's performance rate rather than converting it to a ratio as is done under the Hospital Inpatient Quality Reporting (IQR) and VBP Programs. We finalized that the MSPB measure is added to the total per capita costs for all attributed beneficiaries domain and equally weighted with the total per capita cost measure in that domain. Additionally, we finalized that an MSPB episode is attributed to a single group of physicians that provides the plurality of Part B services (as measured by standardized allowed charges) during the index admission, for the purpose of calculating that group's MSPB measure rate. Finally, we finalized a minimum of 20 MSPB episodes for inclusion of the MSPB measure in a physician group's cost composite.

Additionally, in the CY 2014 PFS final rule with comment period (78 FR 74780), we finalized our proposal to use the specialty adjustment method to create the standardized score for each group's cost measures beginning with the CY 2016 VM. That is, we refined our current peer group methodology to account for specialty mix using the specialty adjustment method. We also finalized our proposal to include this policy in our cost composite methodology. Additionally, we finalized our proposal to identify the specialty for each EP based on the specialty that is listed on the largest share of the EP's Part B claims.

As discussed in the CY 2014 PFS final rule with comment period (78 FR 74781), we submitted the total per capita cost measure for National Quality Forum (NQF) endorsement in January 2013. In the final voting in September 2013, the NQF Cost and Resource Use Committee narrowly voted against the measure by a count of 12 in support and 13 in opposition. We proposed to address two of the major concerns that Committee raised in its review of the measure. First, we proposed modifications to our two-step attribution methodology. Second, we proposed to reverse the current exclusion of certain Medicare beneficiaries during the performance period. We stated that these proposals would apply beginning with the CY

2017 payment adjustment period for the VM and would apply to all five of the total per capita cost measures under § 414.1235(a)(1) through (5) (79 FR 40510). The modifications to the two-step attribution methodology also would apply to the methodology used for attributing beneficiaries for the computation of claims based quality measures under § 414.1230, except for participants in the Shared Savings Program as described later.

The attribution methodology for the five total per capita cost measures and claims based quality measures in the VM, as finalized in the CY 2013 PFS final rule with comment period (77 FR 66318 through 66320), includes two steps. Before applying the two steps, however, we first identify all beneficiaries who have had at least one primary care service rendered by a physician in the group. Primary care services include evaluation and management visits in office, other outpatient, skilled nursing facility, and home settings. After this "pre-step", we assign, under Step 1, beneficiaries to the group practice who had a plurality of primary care services (as measured by allowed charges) rendered by primary care physicians in the group, which include Family Practice, Internal Medicine, General Practice, and Geriatric Medicine. If a beneficiary is non-assigned under Step 1, we proceed to Step 2, which is to assign beneficiaries to the group practice whose affiliated non-primary care physicians, nurse practitioners (NPs), physician assistants (PAs), and clinical nurse specialists (CNSs) together provided the plurality of primary care services (as measured by allowed charges), as long as at least one primary care service was provided by a non-primary care physician in the group.

To address NQF concerns regarding the attribution methodology of the total per capita cost measure, we proposed two modifications to the two-step attribution methodology as applied to the five total per capita cost measures, as well as the claims based quality measures in the VM. NQF Committee members discussed how primary care services often are provided by NPs, PAs, or CNSs, but Step 1 of the attribution methodology assigns beneficiaries to the group who had a plurality of primary care services rendered by primary care physicians in the group. After further consideration, we agreed that it is appropriate to include NPs, PAs, and CNSs in Step 1 of the attribution method insofar as they provide primary care services. Consequently, we proposed to move these NPs, PAs, and CNSs from Step 2 of the attribution

method to Step 1. This change would affect all five of the total per capita cost measures under § 414.1235(a)(1) through (5) and the claims-based quality measures under § 414.1230.

Additionally, we proposed to remove the "pre-step" described above for the purposes of the value modifier. The "pre-step" was included in the Shared Savings Program assignment methodology to comply with the statutory requirement (77 FR 67851) that beneficiary assignment be based upon the utilization of primary care services furnished by a physician. However, no such limitation exists for the VM. Consequently, we proposed to remove the "pre-step" that identifies a pool of assignable beneficiaries that have had at least one primary care service furnished by a physician in the group. Removing the "pre-step" would result in streamlining the attribution process and attributing beneficiaries based on a plurality of primary care services according to Step 1 and Step 2. In addition, we believe that this proposal would help ensure that beneficiaries can be assigned to group practices made up of nonphysician eligible professionals because it would eliminate the criterion that a beneficiary have at least one primary care service furnished by a physician in the group practice. This change (removing the "pre-step") would affect all five of the total per capita cost measures under § 414.1235(a)(1) through (5) and the claims-based quality measures under § 414.1230.

The two-step attribution rule would remain intact after these two modifications, and the method would continue to be generally consistent with the method of assignment of beneficiaries under the Shared Savings Program, as specified under § 414.1240. As discussed previously, the "pre-step" would be removed. We would assign, under Step 1, beneficiaries to the group who had a plurality of primary care services (as measured by allowed charges) rendered by primary care physicians, NPs, PAs, or CNSs in the group. If a beneficiary is non-assigned under Step 1, we still would proceed to Step 2, which would assign beneficiaries to the group practice whose affiliated non-primary care physicians provided the plurality of primary care services (as measured by allowed charges). We proposed these modifications only for groups and solo practitioners who are not participating in the Shared Savings Program. We noted that for groups and solo practitioners who participate in the Shared Savings Program, we would not remove the pre-step or change the attribution methodology for quality

measures and cost measures, but would continue to rely on the methodology used by the Shared Savings Program to attribute beneficiaries to ACOs in the Shared Savings Program. Because we are not applying these assignment changes to Shared Savings Program ACO participants, there is no need to recalculate Shared Savings Program assignment.

One of the reasons we originally proposed this two-step attribution process for the total per capita cost measures and claims based quality measures was that it was aligned with the attribution methodologies used by the Shared Savings Program and also the PQRS GPRO Web interface (77 FR 69318 through 69320). We recognize that these programs may seek to establish changes to their methodologies, and noted that for the purposes of the VM, we intended to retain the two-step beneficiary attribution methodology that was described in the CY 2013 PFS final rule with comment period (77 FR 69318 through 69320), subject to the changes proposed above. However, to address the concerns raised by NQF, we believe the proposed modification to the two-step beneficiary attribution method would more appropriately reflect the multiple ways in which primary care services are provided, which are not limited to physician groups. We welcomed comments on our proposed modification to the two-step attribution methodology as applied to the five total per capita cost measures under § 414.1235(a)(1) through (a)(5) and to the claims-based quality measures under § 414.1230 of the VM.

The following is summary of the comments we received on our proposed modification to the two-step attribution methodology as applied to the five total per capita cost measures under § 414.1235(a)(1) through (5) and to the claims-based quality measures under § 414.1230 for the VM.

Comment: Many commenters opposed our proposal to modify the two-step attribution methodology. The commenters stated that it would not be appropriate to include NPs, PAs and CNSs in the first step of the attribution methodology because these nonphysician practitioners are not necessarily practicing in a primary care setting. The commenters expressed concern that, unlike for physicians, there is no specialty distinction on claims billed by NPs, PAs, or CNSs. Therefore, CMS would not be able to distinguish between those practitioners who are practicing in primary care settings and those who are in non-primary care settings. Commenters

believe that moving NPs, PAs, and CNSs to the first step could result in beneficiaries being attributed to a specialty practice instead of a primary care practice. A few commenters stated that this would unfairly affect the cost measure calculations for specialist groups with large numbers of nonphysician practitioners. We did not receive any comments specifically opposing the removal of the “pre-step” from the methodology. Several commenters supported our proposal to modify the attribution methodology. The commenters stated that it is important to recognize the role of nonphysician practitioners in providing primary care to beneficiaries and that these changes create a methodology that more accurately reflects team-based approaches to care.

Response: We appreciate the concerns raised by commenters about the potential impact that the lack of specialty designation for NPs, PAs, and CNSs could have on the cost and claims based quality measures. However, we do not believe that this is likely to occur. In an analysis of the impact of including NPs and PAs in step 1 of the attribution methodology using 2011 data for groups of twenty-five or more eligible professionals, we found that over 97 percent of beneficiaries were attributed to the same group that they had been attributed to under the current methodology. Although this analysis does not exactly replicate the changes we proposed, we believe it is a reasonable indication that the changes will not have the significant impact predicted by commenters. We are conducting additional analysis and will monitor the effect of these changes to ensure they are not having a disproportionately negative effect on a subset of provider types. We appreciate the support of and agree with commenters who believe it is important to recognize the role that many NPs, PAs, and CNSs play as primary care providers. The analysis referenced earlier also found that the inclusion of NPs and PAs in step 1 resulted in an increase of 2.55 percent to the number of beneficiaries attributed to a group and the number of groups to which at least 20 beneficiaries were attributed increased by 3.4 percent. For these reasons, we agree with the NQF recommendation to include these nonphysician practitioners in the attribution methodology. Further, this attribution change will become even more important as we expand the application of the VM to smaller groups and solo practitioners, to increase the number of patients whom they can be

assigned, to receive a cost composite that is other than “average” under the VM.

We are finalizing our policy as proposed. Beginning in the CY 2017 payment adjustment period, we will move NPs, PAs, and CNSs from step 2 of the attribution method to step 1. Additionally we are removing the pre-step under which we first identify all beneficiaries who have had at least one primary care service rendered by a physician in the group. These changes apply to all five total per capita cost measures under § 414.1235(a)(1) through (5) and the claims-based quality measures under § 414.1230.

Second, NQF committee members raised concerns about the exclusion of certain beneficiaries in the methodology used for the total per capita cost measure. Committee members expressed concern that end-of-life costs were not being captured by the measure. We considered this argument and agreed that it is important to include certain beneficiaries with these costs during the performance period. As a result, we proposed to include certain part-year Medicare FFS beneficiaries. This change would affect all five of the total per capita cost measures under § 414.1235(a)(1) through (a)(5). The change would provide a more complete assessment of end of life costs associated with the patients a physician group sees during the year (79 FR 40510).

We proposed to continue excluding other part-year beneficiaries (those who spend part of the performance period in a Medicare Advantage (Part C) plan and those enrolled in Part A only or Part B only for part of the performance period and both Part A and Part B for the remainder of the performance period) (79 FR 40511). Since 2012 we have applied the same attribution rule as that used for the Medicare Shared Savings Program and the PQRS GPRO Web Interface (77 FR 69318–20). In this regard, excluding part-year Medicare Advantage enrollees would remain consistent with the Shared Savings Program and PQRS GPRO Web interface reporting policy. If we were to include these part-year Medicare Advantage enrollees, we would need to determine a method to impute their costs for the portion of the performance period in which they were enrolled in FFS Medicare Parts A and B so that we could compare beneficiaries’ annual per capita costs appropriately. Similarly, Medicare Part A only or Medicare Part B only enrollees who were enrolled in both Part A and Part B for only part of the performance period would also require a method to impute their costs if they

were no longer excluded. Furthermore, these Part A only or Part B only beneficiaries are excluded from the Shared Savings Program and PQRS GPRO methodology.

We proposed including Medicare FFS beneficiaries who are newly enrolled to Medicare during the performance period and enrolled in both Part A and Part B while in Medicare FFS. Additionally, we noted that while the inclusion of new enrollees is inconsistent with GPRO's methodology, it would be consistent with the Shared Savings Program's methodology (79 FR 40511). We welcomed comments on the inclusion of these part-year beneficiaries. We also welcomed comments on whether other part-year Medicare FFS beneficiaries (that is, those who are part-year Medicare Advantage enrollees or part-year Medicare Part A only or Part B only enrollees) should be included in the five total per capita cost measures under § 414.1235(a)(1) through (5) in the VM.

Comment: Some commenters opposed our proposal to include certain part-year Medicare FFS beneficiaries in the five total per capita cost measures because they believe the inclusion of these typically higher cost beneficiaries would inappropriately disadvantage groups that treat a large percentage of beneficiaries at the end of life. We also received comments in support of our proposal to include certain part-year beneficiaries. These commenters stated that it is important to include as many Medicare beneficiaries in the cost measure calculations as feasible and especially important to capture the often significant costs incurred by beneficiaries at the end of life. One commenter suggested that we should develop an end of life specific cost and quality measure rather than including these costs in the per capita cost measures. We did not receive any comments in opposition to the inclusion of newly eligible beneficiaries in the five total per capita cost measures. One commenter indicated that they do not understand why we would exclude any of the part-year beneficiaries, stating that if we can impute costs for some part-year beneficiaries, we should be able to do so for all part-year beneficiaries.

Response: We appreciate the support of commenters who supported our proposal to include some part-year beneficiaries in the five total per capita cost measures. Part-year beneficiaries include those who receive end-of-life care, which has been correlated with

high-cost episodes of care.²⁴ However, analysis submitted to the Institute of Medicine produced an inconclusive causal relationship between the end of a beneficiary's life and the cost of that care.²⁵ Indeed, research refutes the assumption that Medicare beneficiaries near the end of life have substantially similar health statuses.²⁶ Rather, prior diagnoses, a characteristic that we currently adjust for in the VM, accounts for a substantial percentage of the geographic variation in the end-of-life costs. In other words, we believe that the risk adjustment system under the VM program explains approximately the same extent of costs in the general Medicare population as it does for the cohort of Medicare beneficiaries near the end of life.²⁷ In response to concerns raised by commenters, we conducted additional analyses to ensure the inclusion of part-year beneficiaries does not inappropriately negatively impact certain groups or solo practitioners. This analysis, which we plan to post to the Value Modifier Web site in the near future, showed moderate reliability for the five per capita cost measures continued to be high with the inclusion of certain part-year beneficiaries. For example, for the overall per capita cost measure, 83 percent of TINs had reliability equal to or higher than 0.4 when these part-year beneficiaries were included. We agree that it is important to capture as many beneficiaries and costs in these measures as is reasonably possible especially as the number of beneficiaries new to Medicare increases and we continue to agree with the NQF's recommendation to capture end of life costs in our measures. We believe that the inclusion of newly eligible beneficiaries, who are typically much lower cost and a growing portion of the Medicare program, may offset some of the increased costs associated with beneficiaries at the end of life. We appreciate the suggestion to include cost and quality measures that specifically

measure care at the end of life and will take this into consideration as we continue to develop the VM program. We also appreciate the comments in support of including other part-year beneficiaries in our measures and we will continue to look into this possibility.

We are finalizing our policies as proposed. Beginning in the CY 2017 payment adjustment period, we will include certain part-year beneficiaries in the five total per capita cost measures under § 414.1235(a)(1) through (5). These part-year beneficiaries include Medicare FFS beneficiaries who are at the end of life in the performance period and Medicare FFS beneficiaries who are newly enrolled in Medicare during the performance period and enrolled in both Part A and Part B while in Medicare FFS.

In this final rule with comment period, we chose not to address the other concerns about the total per capita cost measures that were raised by NQF. First, we deferred addressing the issue of whether to incorporate socioeconomic status in our measures until after the NQF has finalized its guidance regarding risk adjustment for resource use measures. Second, we did not propose to include Part D data in the total per capita cost measures at this time due to the complexity of the issue and uncertainty of how to fairly and equitably incorporate the costs. Based on data compiled by the Medicare Payment Advisory Commission (MedPAC), we estimated that approximately 60 percent of Medicare FFS beneficiaries were enrolled in stand-alone Part D in 2013.²⁸ A significant minority of beneficiaries has prescription drug coverage from a source that is outside of Medicare—such as through retiree coverage from a former employer—but for which Medicare does not have access to the data. Including Part D data would incorrectly indicate higher costs for these beneficiaries with Part D coverage relative to otherwise comparable beneficiaries without such coverage and for whom prescription drug costs cannot be measured directly by CMS. Before we are able to propose inclusion of Part D data, we would need to determine an

²⁴ Congressional Budget Office, "High-Cost Medicare Beneficiaries." Final Paper (May 2005), available at <http://www.cbo.gov/sites/default/files/05-03-medispending.pdf>.

²⁵ Acumen, "Geographic Variation in Spending, Utilization and Quality: Medicare and Medicaid Beneficiaries" (May 2013), available at <http://www.iom.edu/Reports/2013/-/media/Files/Report%20Files/2013/Geographic-Variation/Sub-Contractor/Acumen-Medicare-Medicaid.pdf>.

²⁶ Reschovsky JD, et al. "Geographic Variation in Fee-for-Service Medicare Beneficiaries' Medical Costs Is Largely Explained by Disease Burden." *Med. Care Res. & Rev.* 2013; XX,1–22.

²⁷ Medicare decedents and Medicare survivors with similar diagnoses and utilization in the previous year had substantially similar cost profiles. Hogan C, et al. "Medicare Beneficiaries' Costs of Care In the Last Year Of Life." *Health Affairs.* 2001; 20, 188–195.

²⁸ Please see http://www.medpac.gov/documents/Mar14_EntireReport.pdf for underlying data. We estimated that there were 37.3 million Medicare FFS beneficiaries by subtracting the number of beneficiaries enrolled in Medicare Advantage (14.5 million) from the estimated total number of Medicare beneficiaries using data in table 13–1 (P. 328). We estimated that there were 22.4 million beneficiaries with a stand-alone prescription drug plan, which represented 64 percent of the 35 million beneficiaries with Medicare Part D coverage (p. 355).

approach to address this issue. We welcomed comments on suggested methods for including Part D data in the total per capita cost measures.

Comment: Many commenters expressed concern that we are not currently including Part D expenditures in our cost measures. These commenters stated that the exclusion of Part D costs could push providers to prescribe Part D drugs even when the Part B drug is more appropriate for the patient. Additionally, commenter stated that they believe the exclusion of Part D unfairly harms providers that see sicker patients because they believe that these patients are more likely to require Part B medications. Several commenters suggested that CMS either include Part D costs or exclude Part B drug costs. Others suggested excluding only those Part B costs for drugs that have a Part D equivalent or capping the Part B costs for certain high cost drugs. We did not receive any comments specifically recommending an approach for how Part D costs could be included in our cost measurement.

Response: We appreciate the comments and understand the concerns raised in regard to exclusion of Part D costs. We remain committed to capturing a full picture of the total cost of care and to assessing cost in a fair and consistent manner. We are actively investigating options for operationally including Part D costs in our cost measures and would propose any viable options under future notice and comment rulemaking.

Comment: We received many comments emphasizing the importance of including socioeconomic status in our measures. Commenters believe that this is critical to accurately comparing performance between providers that serve different populations. One commenter stated that socioeconomic status should be used in risk adjusting outcomes measures but should not be used in process measures.

Response: As noted above, we will continue to consider whether it would be appropriate to apply a socioeconomic status adjustment to the measures included in the VM. In August 2014, NQF released a report on this topic with recommendations for the development of socioeconomic risk adjustment methodologies.²⁹ Consistent with that report, we believe it is important to proceed cautiously on this question. We will take the recommendations in this

report into account as we consider potential future refinements to our risk adjustment methodologies. Any changes would be made through rulemaking.

We also received the following comment, which we believe is outside of the scope of our proposals:

Comment: One commenter stated that CMS should revise our attribution methodology to look at “allowed services,” rather than “allowed charges.” The commenter believes that by looking at “allowed charges” we may be inaccurately attributing beneficiaries to the provider that bills using higher level E&M codes, rather than the provider that sees the patient most often.

Response: We believe that a focus on allowed charges is appropriate for attribution in Medicare payment measures, because the intent is to assess which eligible professional should be held accountable for the payments made. Further, the use of allowed charges in the scenario presented by the commenter would further incentivize providers to correctly code E&M services rendered.

k. Discussion Regarding Treatment of Hospital-Based Physicians

We considered including or allowing groups that include hospital-based physicians or solo practitioners who are hospital-based to elect the inclusion of Hospital Value-Based Purchasing (VBP) Program performance in their VM calculation in future years of the program. We stated that would include hospital performance for the hospital or hospitals in which they practice. We would propose such a change through future notice and comment rulemaking, taking into consideration public comment and any relevant empirical evidence available at that time. We considered this potential policy to expand the performance data included for hospital-based physicians and to better align incentives for quality improvement and cost control across CMS programs. Such a policy would also address public comments we received on the CY 2014 PFS proposed rule (78 FR 74775), suggesting that the Hospital VBP Program total performance score for the hospital in which a specialist practices should be used in the VM. Commenters made this suggestion, noting that there were limited measures that apply to certain specialties and that those specialties may exercise wide influence over the quality of care provided in a hospital. We noted that a hospital’s final Hospital VBP Program performance for a given performance period would not be available to a group at the time that they

registered for PQRS reporting, so if we were to establish a voluntary policy where groups could elect to include hospital performance, they would make the election to have that performance included in their VM for a payment adjustment period based on the hospital’s historic VBP Program performance which would be known to the TIN at the time of election.

We sought public comment on the appropriate methodology to identify hospital-based groups and solo practitioners for the purpose of having Hospital VBP Program data included or allowing them to elect inclusion of Hospital VBP Program performance data in the VM at the TIN level (70 FR 40511–40512). We suggested that we could either allow self-nomination or set a threshold based on physician billing, in order to determine whether a given physician was hospital-based. We sought comment on whether we should set a threshold for a certain proportion of a group’s physicians that would have to meet the criteria, in order for hospital-level performance to be included in the group’s VM calculation. We also sought comment on whether to use a set of criteria to determine whether non-physician eligible professionals should be allowed to self-nominate or should automatically have hospital-level performance data included in the calculation of their VM. We requested public comment on potential methods for determining which hospital or hospitals’ Hospital VBP Program performance data should be included in a physician TIN’s VM and how to weight the hospitals, if more than one was included (79 FR 40512). We welcomed public comment on the approaches we considered, as well as alternative approaches for inclusion of all or part of the Hospital VBP Program TPS into the VM. In the interest of aligning the HVBP and VM programs, we sought public comment on what criteria we should consider in selecting a subset of Hospital VBP Program measures or domains in the VM, if we were to adopt such a policy. Finally, we requested public comment on the most appropriate approach for including Hospital VBP Program performance into a TIN’s VM.

Comment: Commenters generally supported including the Hospital VBP Program performance in the VM, suggesting that it be made voluntary for physicians who meet some threshold of services rendered in the hospital setting. Commenters stated that a 90 percent threshold would be too high.

Response: We appreciate the comments and will take these into consideration as we continue to refine

²⁹ National Quality Forum, “Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors.” Final Report (2014), available at http://www.qualityforum.org/Publications/2014/08/Risk_Adjustment_for_Socioeconomic_Status_or_Other_Sociodemographic_Factors.aspx.

the VM program and improve the coordination between the HVBP and VM programs. We would propose any policy changes through future notice and comment rulemaking.

5. Physician Feedback Program

Section 1848(n) of the Act requires us to provide confidential reports to physicians (and, as determined appropriate by the Secretary, to groups of physicians) that measure the resources involved in furnishing care to Medicare FFS beneficiaries. Section 1848(n)(1)(A)(iii) of the Act also authorizes us to include information on the quality of care furnished to Medicare FFS beneficiaries.

a. CY 2013 Quality and Resource Use Reports Based on CY 2013 Data and Disseminated in CY 2014

In September 2014, we made available the QRURs based on CY 2013 data to all physicians (that is, TINs of any size) even though groups with fewer than 100 eligible professionals will not be subject to the VM in CY 2015. These reports provide clinically meaningful and actionable information on several aspects of the performance of a group practice or solo practitioner. The reports present not only data assessing a group practice's or solo practitioner's performance on cost measures and information about the services and procedures contributing most to beneficiaries' costs, but also provide data on their performance on quality measures they report under the PQRS as well as the three outcome measures under § 414.1230. For groups of 100 or more eligible professionals that are subject to the VM starting in 2015, the QRURs provide information on how the group's quality and cost performance affects their physicians' Medicare payments in 2015. The reports also contain additional supplementary information on the specialty adjusted benchmarks; inclusion of the individual PQRS measures for informational purposes for EPs reporting PQRS measures as individuals; enhanced drill down tables; and a dashboard with key performance measures. The reports are based on the VM policies that were finalized in the CY 2013 PFS final rule (77 FR 69310) for physician payment adjustments under the VM beginning January 1, 2015, and they provide groups with an opportunity to see how the policies adopted will apply to them.

b. Episode Costs and the Supplemental QRURs

Section 1848(n)(9)(A) of the Act requires CMS to develop an episode grouper and include episode-based costs

in the QRURs. An episode of care consists of medical and/or procedural services that address a specific medical condition or procedure that are delivered to a patient within a defined time period and are captured by claims data. An episode grouper organizes administrative claims data into episodes.

We developed a prototype set of episodes that expands upon the set of episodes that were described in the CY 2014 PFS final rule with comment period (78 FR 74785). In summer 2014, we distributed Supplemental QRURs based on 2012 data to a greater number of groups (groups with at least 100 EPs³⁰ EPs) that included a broader set of episodes than the 2011 Supplemental QRURs. In addition to the five clinical conditions in the 2011 Supplemental QRURs, the 2012 Supplemental QRURs included: Chronic congestive heart failure (CHF); chronic obstructive pulmonary disease (COPD)/asthma; acute COPD/asthma; permanent pacemaker system replacement/insertion; and bilateral cataract removal with lens implant. For the 2012 Supplemental QRURs, we broke down these episode types into 20 subtypes altogether. In addition to these 20 episode subtypes, we included in the 2012 Supplemental QRURs 6 clinical episode-based measures that we are adapting from those considered for inclusion in the Hospital VBP program (79 FR 28122 through 28124). We described the 20 episode subtypes and six clinical episode-based measures in the proposed rule and sought comment on the three medical and three surgical episode measures that we included in the 2012 Supplemental QRURs.

We did not receive any general comments on the three medical and three surgical episode measures that we included in the 2012 Supplemental QRURs.

Attribution for the six clinical episode-based measures at the group level are the same as the rules used for comparable types of the 20 episode subtypes in the 2012 Supplemental QRURs as discussed above. Attribution rules varied depending on whether a clinical episode-based measure was one of the three surgical (or procedural) episodes or one of the three medical (or acute condition) episodes. Further details on attribution rules can be found

³⁰ For Supplemental QRUR purposes, groups were also included if they did not participate in multiple accountable care organizations (ACOs) and did not participate in more than one of the following initiatives in program year 2012: The Shared Savings Program, the Pioneer Accountable Care Organization (ACO) Model, or the Comprehensive Primary Care Initiative (CPCI).

in "Detailed Methods of the 2012 Medical Group Practice Supplemental Quality and Resource Use Reports (QRURs)" at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Episode-Costs-and-Medicare-Episode-Grouper.html>.

Specifications for these six clinical episode-based measures, including the MS-DRG and procedure codes used to identify each of the episodes, and details of episode construction methodology, are available in "Detailed Methods of the 2012 Medical Group Practice Supplemental Quality and Resource Use Reports (QRURs)" at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Episode-Costs-and-Medicare-Episode-Grouper.html>. We welcomed public comments on these specifications and the construction of the six clinical episode-based measures that we included in the 2012 Supplemental QRURs.

The following is summary of the comments we received on these specifications and the construction of the six clinical episode-based measures that we included in the 2012 Supplemental QRURs.

Comment: One commenter stated that because E&M services are used as the basis for attribution for acute and chronic episodes, they believe it is unlikely that most radiology groups would have a score calculated for these measures. The commenter also noted that certain procedural episode measures, not currently under consideration for inclusion in the VM, may be calculated for radiology groups. Another commenter stated that he believes there are inconsistencies and errors in the attribution methodology used for episode measures.

Response: We understand the concerns of specialists, including radiology groups, about the challenge of identifying measures for which they would have a sufficient number of attributed beneficiaries to have the measures calculated. We will take these into consideration as we continue to refine the measures and consider them for future use in the VM.

CMS' episodes will continue to evolve over the coming years as more experience is gained. More information about the Supplemental QRURs can be found at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Episode-Costs-and-Medicare-Episode-Grouper.html>.

We will continue to seek stakeholder input as we develop the episode

framework. We considered proposing to add episode-based payment measures to the VM through future rulemaking for all 12 episode subtypes, or some subset of these episode subtypes, of the selected respiratory and selected heart conditions that have appeared in both the 2011 Supplemental QRURs and 2012 Supplemental QRURs. These 12 episode subtypes include: Pneumonia (all), pneumonia without an inpatient hospitalization, pneumonia with an inpatient hospitalization, acute myocardial infarction (now called acute coronary syndrome or ACS), ACS without percutaneous coronary interventions (PCI) or coronary artery bypass graft (CABG), ACS with PCI, ACS with CABG, coronary artery disease (now called ischemic heart disease or IHD), IHD without ACS, IHD with ACS, CABG without preceding ACS, and PCI without preceding ACS. Additionally, we are considering proposing to add hospital episode-based payment measures to the VM at a later time, such as the six hospital episodes described above. We welcomed public comments on the specifications included on the Web site and the construction of the episode-based payment measures that we considered.

The following is summary of the comments we received on the specifications included on the Web site and the construction of the episode-based payment measures that we considered.

Comment: Several commenters supported our continued efforts to develop episode-based payment measures. Two of these commenters indicated that they believe these measures will support better coordination of care across settings. One commenter suggested that the development of episode measures should follow a similar process to that used for quality measures, including multi-stakeholder expert consensus, evidence-based medicine, and clinical guidelines, as appropriate. We received a few comments stating that the episode measures should not be included in the VM at this time. Two commenters stated their belief that the episode measures are not currently tied to quality measures and suggested that we address that concern before incorporating the measures into the VM. Another commenter stated that they believe the episode measures are duplicative of the care already captured in the MSPB measure and expressed concern about the reliability of the measures. This commenter suggested that these measures should be removed from the supplemental QRURs until these reliability concerns are addressed.

Another commenter suggested that CMS conduct a more thorough analysis of the attribution methodology used in the episode measures and that we narrow the scope of the conditions that are currently included in the episode measures before introducing them into the VM.

Response: We appreciate the input of commenters. We share the commenters' beliefs that coordination across care settings is an important factor in improving quality of care and cost performance. We understand the concerns raised about duplication across cost measures and will take that and the other feedback we received regarding attribution, tying the cost measures to quality measures and the vetting process for measures as we continue to refine the measures and consider them for future use in the VM. Developing a more robust set of cost measures for the VM remains an important goal.

c. Future Plans for the Physician Feedback Reports

In the proposed rule, we stated that we will continue to develop and refine the annual QRURs in an iterative manner and we will seek to further improve the reports by welcoming suggestions from our stakeholders.

As noted previously, on September 30, 2014, we made available the QRURs based on CY 2013 data to all physicians (that is, TINs of any size) even though groups with fewer than 100 eligible professionals will not be subject to the VM in CY 2015. These reports contain performance on the quality and cost measures used to score the composites and additional information to help physicians coordinate care and improve the quality of care furnished. We also intend to provide semi-annual reports with updated cost and utilization data. We will again solicit feedback from physicians and continue to work with our partners to improve them. We note that physicians will have some time to determine the impact of our revised policies and revise their practices accordingly before the new policies impact them. We look forward to continue working with the physician community to improve the QRURs.

We received the following general comments on the Physician Feedback Program:

Comment: Many commenters stated their support for the Physician Feedback Program and applauded CMS's efforts to improve the QRURs. Many commenters stated that we should provide QRURs to providers earlier in the year to give them more time to analyze the results and make adjustments prior to the

following calendar year. Several commenters also suggested that QRURs should be distributed to all providers, including nonphysician eligible professionals. Some commenters suggested that CMS increase our education and outreach efforts to ensure that providers know how to access and use the QRURs.

Response: We appreciate commenters support for the Physician Feedback Program and we will take these comments into consideration as we continue to develop and improve the Physician Feedback Program. While it is not feasible to provide the annual QRURs earlier in the year while still allowing sufficient time for claims run out and reporting period, we are exploring how to provide semi-annual reports that will allow groups and solo practitioners to better track their performance on cost and utilization during the year.

O. Establishment of the Federally Qualified Health Center Prospective Payment System (FQHC PPS)

In the May 2, 2014 **Federal Register**, we published the final rule with comment period (79 FR 25436) entitled "Medicare Program; Prospective Payment System for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics; and Changes to Clinical Laboratory Improvement Amendments of 1998 Enforcement Actions for Proficiency Testing Referral; Final Rule" (herein, "FQHC PPS final rule"). This final rule with comment period implemented methodology and payment rates for federally qualified health center (FQHC) services under Medicare Part B beginning on October 1, 2014, in compliance with the statutory requirement of the Affordable Care Act, and contained other provisions. In this final rule with comment period, we invited comments on how payment for chronic care management (CCM) services could promote integrated and coordinated care in FQHCs and rural health clinics (RHCs). We also invited comments on the modification of our proposed policy to allow exceptions to the FQHC PPS per diem payment for subsequent illness or injury and mental health services furnished on the same day as a medical visit; the establishment of FQHC G-codes to report and bill FQHC visits to Medicare under the PPS; and the modification of our proposed approach to waiving coinsurance for preventive services when furnished with other services under the FQHC PPS.

1. Promoting Integrated and Coordinated Care in FQHCs and RHCs Through Payment for Chronic Care Management (CCM) Services

In the FQHC PPS final rule with comment period, we invited comments from FQHCs and RHCs on how payment for CCM services could help to promote integrated and coordinated care in FQHCs and RHCs. We cited the CCM information in the CY 2014 PFS final rule with comment period (78 FR 74230) for physicians billing under the PFS in 2015. We encouraged FQHCs and RHCs to review this information and submit comments to us on how the CCM services payment could be adapted for FQHCs and RHCs to promote integrated and coordinated care.

We received a few comments regarding how the CCM services payment could be adapted for FQHCs in CY 2015 to provide integrated and coordinated care in FQHCs. Commenters supported adopting the CCM provisions in FQHCs but had concerns about the unique challenges FQHCs would face implementing these provisions. The following is a summary of these comments.

Comment: Commenters stated that the seven initiatives outlined in the CY 2014 PFS final rule with comment period are viable in FQHCs, but noted that FQHCs would face unique challenges when implementing this provision. Commenters stated that the provisions requiring electronic exchange of information might prove difficult at this time since many FQHCs are using electronic health records but are still working on developing the interoperability with other providers. Commenters suggested the requirement to provide patients with secure messages via the internet would be difficult since many FQHC patients are at or below 200 percent of the federal poverty level (FPL) and do not have access to internet or email. For example, a commenter stated that 94 percent of all FQHC patients in one state were below 200 percent of the FPL in 2012. Commenters supported adopting these provisions for FQHCs and suggested that we implement requirements that do not place an undue burden on the health centers or the patient population. One commenter urged that the additional G-codes for CCM services be sufficient to cover the associated costs of documenting care coordination and another commenter expressed concern for appropriate payment and requested that we develop a risk-adjusted per patient per month CCM fee.

Response: We appreciate the comments and will take them into consideration.

2. Exceptions to the Per Diem FQHC PPS Payment for Subsequent Illness or Injury and Mental Health Services Furnished on the Same Day as a Medical Visit

FQHCs receive enhanced payment to reflect all costs associated with a visit in a single day by a Medicare beneficiary, regardless of the length or complexity of the visit or the number or type of practitioners seen. Under the all-inclusive rate (AIR) system, an exception to the one encounter payment per day policy was made for situations when a patient comes into the FQHC for a medically necessary visit, and after leaving the FQHC, has a medical issue that was not present at the visit earlier that day, such as an injury or unexpected onset of illness. In these situations, the FQHC has been paid separately for two visits on the same day for the same beneficiary. Under the AIR system, we also allowed separate payment for mental health services furnished on the same day as a medical visit, separate payment for diabetes self-management training/medical nutrition therapy (DSMT/MNT), and separate payment for the initial preventive physical exam (IPPE).

In the FQHC PPS proposed rule, published in the September 23, 2013 **Federal Register** (78 FR 58386), we stated that 2011 Medicare FQHC claims data was reviewed to determine the frequency of FQHCs billing for more than one visit per day for a beneficiary, and we analyzed the potential financial impact on both FQHCs and on access to care if billing for more than 1 visit per day for these situations was no longer permitted. We also considered several alternative options, such as an adjustment of the per visit rate when multiple visits occur in the same day, or the establishment of a separate per visit rate for subsequent visit due to illness or injury, mental health services, DSMT/MNT, or IPPE.

An analysis of data from Medicare FQHC claims with dates of service between January 1, 2011 and June 30, 2012, indicated that multiple visits billed on the same day constituted less than 0.5 percent of all visits, even though the ability to do so has been in place since 1992 for subsequent illness/injury, since 1996 for mental health services, and since 2007 for DSMT/MNT. We concluded that even allowing for any underreporting in the data, eliminating the ability to bill for multiple visits on the same day would not significantly impact either the

FQHC payment or a beneficiary's access to care. Therefore, we proposed to revise § 405.2463(b) to remove the exception to the single encounter payment per day for FQHCs paid under the proposed PPS, and we stated that this policy is consistent with an all-inclusive methodology and reasonable cost principles and would simplify billing and payment procedures.

In the FQHC PPS proposed rule, we solicited comments to address whether there are factors that we have not considered, particularly in regards to the provision of mental health services, and whether this change would impact access to these services or the integration of services in underserved communities.

Although we did not receive any information that showed a direct link between multiple billing on the same day and increasing access to care, we modified our proposal in the final rule and stated that we will allow separate billing for subsequent illness or injury occurring on the same day as another medical visit. We also modified our proposal in the FQHC PPS final rule to allow separate billing for mental health services furnished on the same day as a medical visit, as the comments we received led us to conclude that this had the potential to increase access to care, even if the current claims data did not show that this option was being utilized. We invited comments on these modifications.

We received many comments on the modifications to our proposed policy, which would allow an exception to the per diem PPS payment for subsequent injury or illness and for mental health services furnished on the same day as a medical visit. All of the commenters were supportive of this modification; however, most of the commenters requested additional exceptions to the per diem PPS payment. The following is a summary of these comments.

Comment: Most commenters strongly supported our decision to allow separate payment for subsequent injury or illness and mental health services furnished on the same day as a medical visit. Commenters stated that allowing separate payment for mental health services when primary care services are furnished would facilitate integrated and comprehensive health care to Medicare beneficiaries, and agreed with our assertion that separate payment for mental health services has the potential to increase access to mental health services in underserved areas. The commenters also stated that our modification demonstrated our commitment to the value of furnishing mental health services in FQHCs.

Many of the commenters who supported our modification allowing subsequent injury or illness and mental health services to be billed separately when furnished on the same day as another billable visit also requested additional exceptions to the PPS per diem payment system. They noted that under the AIR payment system, DSMT/MNT services and the IPPE can be billed separately when furnished on the same day as another billable visit, and requested that these services also have an exception under the PPS. Commenters particularly emphasized the need for separate payment for DSMT/MNT services and suggested that not being able to bill separately for a DSMT/MNT visit that occurs on the same day as another billable medical visit would deter efficient provision of these services.

Response: We appreciate the support for allowing an exception to the per diem payment when a subsequent injury or illness occurs and for mental health services furnished on the same day as a medical visit.

Commenters are correct that IPPE and DSMT/MNT can be billed as a separate visit under the AIR payment system when furnished on the same day as another medical visit, and that we did not include IPPE or DSMT/MNT in the exceptions under the PPS. As explained in the FQHC PPS proposed rule, an analysis of claims data from FQHCs indicated that the estimated cost per encounter was approximately 33 percent higher when a FQHC furnished care to a patient that was new to the FQHC or to a beneficiary receiving an IPPE or an annual wellness visit (AWV). If we allowed FQHCs to bill separately for an IPPE that occurred on the same day as another medical visit, we would be overpaying the FQHC for the cost of the IPPE. To accurately pay FQHCs for the costs of furnishing an IPPE, we added an adjustment factor of 1.333 to the PPS rate when an IPPE is furnished at a FQHC. We also extended the adjustment factor to both initial and subsequent AWVs, in order to appropriately compensate FQHCs for the costs of furnishing these services.

In the FQHC PPS proposed rule and final rules, we discussed that we did not include an exception to the per-diem payment for DSMT/MNT because an analysis of the claims and cost reporting data did not justify either a separate per-diem payment or an adjustment to the PPS rate. We also stated our belief that a DSMT/MNT visit is part of the broad category of primary care services that are included in the services of a FQHC and are part of the PPS per diem payment. We noted that visits with

multiple practitioners that occur on the same day, including visits for different conditions or visits with a specialist physician, are not separately payable in a FQHC, and we do not believe that DSMT/MNT visits should be considered differently than other primary care services.

Although the comments we received did not persuade us to allow DSMT/MNT to be billed separately in a FQHC when it occurs on the same day as another billable medical visit, or to add an adjustment to the PPS rate for DSMT/MNT when it is furnished on the same day as another billable visit, we believe it is a valuable service, particularly in FQHCs that serve areas with high rates of people with diabetes and related illnesses, and we encourage FQHCs to furnish this service as necessary.

We are retaining § 405.2463(c)(4)(i) and § 405.2463(c)(4)(ii) as finalized in 79 FR 25478, which states that for FQHCs billing under the PPS, Medicare pays for more than 1 visit per day when the patient (i) suffers an illness or injury subsequent to the first visit that requires additional diagnosis or treatment on the same day; or (ii) has a medical visit and a mental health visit on the same day.

3. Establishment of FQHC G-Codes To Report and Bill FQHC Visits to Medicare Under the PPS

In the FQHC PPS proposed rule (78 FR 58386), we cited section 1833(a)(1)(Z) of the Act and proposed that Medicare payment under the FQHC PPS would be 80 percent of the lesser of the provider's actual charge or the PPS rate. Commenters were concerned that comparing actual charges with a bundled PPS rate would distort the true cost of services furnished and would result in FQHCs either being forced to increase their charges, or receive payment far below actual cost of furnishing services. In response to these comments, we established a new set of HCPCS G-codes to report an established Medicare patient visit, a new or initial patient visit, and an IPPE or AWV.

We stated that a FQHC would set its charge for the specific payment codes based on its own determination of what would be appropriate for the services normally provided and the population served at that FQHC, and that the charge for a specific payment code would reflect the sum of regular rates charged to both beneficiaries and other paying patients for a typical bundle of services that would be furnished per diem to a Medicare beneficiary. We emphasized that the use of these payment codes does not dictate to providers how to set their charges, and that detailed HCPCS coding with the associated line item

charges would continue to be required along with the payment codes when billing Medicare under the PPS.

Medicare would pay FQHCs 80 percent of either the actual charge reported for the specific payment code or the PPS rate on each claim, whichever is lower.

We stated that establishing HCPCS G-codes for FQHCs to report and bill for Medicare visits would allow comparison between the PPS per diem rate and a FQHC's charge for a per diem visit (as defined by the specific payment codes), and that this would be responsive to commenters' concerns. As we did not propose the establishment of HCPCS G-codes in the proposed rule, nor did we receive public comments specifically requesting such codes, we invited comments on the establishment of G-codes for FQHCs to report and bill FQHC visits to Medicare under the FQHC PPS.

We received several comments on the establishment of G-codes for FQHCs to report and bill FQHC visits to Medicare under the FQHC PPS. Most commenters favored using G-codes to report and bill FQHC visits under the PPS; however, commenters expressed concerns about the complexity and administrative burden of implementing these codes. The following is a summary of these comments.

Comment: Commenters appreciated that we carefully considered the comments related to the Medicare claims payment process and prefer our development of FQHC payment G-codes to compare the FQHC PPS encounter-based rate with the FQHC's actual charges. Commenters stated that the use of G-codes to implement the "lesser of" provision of the statute is a positive solution that allows for parity between the PPS payment rate and the actual charges being compared. Commenters stated that we resolved what they believe would have resulted in an "apples to oranges" comparison by implementing a system that compares the PPS per diem rate, defined by the specific payment HCPCS G-codes, to a FQHC's actual charge for a per diem visit.

Although many of the commenters were supportive of the establishment of G-codes for FQHCs to report and bill FQHC visits to Medicare under the FQHC PPS, many of these commenters stated that the process of developing charges for typical bundles of services will be complex for FQHCs. Commenters stated that FQHCs have had limited experience working with payors who use a "lesser of" or "actual charges" payment methodology. Commenters acknowledged that Medicare regulations require that

charges must be neutral among payors; however, given that other payors and paying patients would not be purchasing a precise bundle of services corresponding to the Medicare FQHC visit, commenters stated that the policy to develop G-codes charges is not straightforward. Commenters stated that the charges developed for the FQHC payment G-codes would not be used for any non-Medicare patient. Commenters also stated that it would be challenging for FQHCs to develop charges for a typical bundle of services and adhere to requirements under section 330 of the Public Health Service (PHS) Act, which requires FQHCs to develop charges consistent with locally prevailing rates that cover their reasonable costs of operation. Commenters stated that in developing actual charges, FQHCs would need to perfect their coding capabilities and appropriately capture the bundle of services they provide in the charges. Although some commenters emphasized the complexity of developing G-code charges, a few commenters appreciated that we did not establish precise methods for FQHCs to develop their own G-code charges.

Response: We understand that developing G-codes for FQHC payment under the PPS is unfamiliar to FQHCs. To assist FQHCs in understanding the new payment system, we held two national training sessions which provided detailed examples of various billing scenarios. A transcript of the presentations and slides from the presentation are posted on our Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FQHCPPS/index.html>. Additional information is available in the “Medicare Benefit Policy Manual, Chapter 13—Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Services,” and the “Medicare Claims Processing Manual, Chapter 9—Rural Health Clinic (RHC)/Federally Qualified Health Center (FQHC).” In the resources, we discuss the need for each FQHC to select a bundle of services that reflects a typical bundle of services that they would provide to a new or established Medicare patient at their FQHC for medical and mental health services and IPPE and AWV. We also address how FQHCs set their own charges (which must be consistent with the requirements under section 330 of the PHS Act when applicable), and since charges must be the same for all patients, the charges for the services that are included in the bundle would be totaled to determine the G-code payment amount. We expect that once FQHCs set their charges and select the

bundle of services that will be included in the FQHC G-codes, they will adapt well to the process. We would also note that other payors could choose to utilize the FQHC payment G-codes if they choose.

Comment: Many commenters suggested that the use of FQHC payment G-codes would create an additional administrative burden for FQHCs’ coding and billing staff. Commenters stated that FQHCs will need to spend additional time explaining the charges on the Explanation of Benefits (EOB) to Medicare beneficiaries since there could be additional charges beyond what the beneficiary typically sees associated with a visit. Some commenters stated that using FQHC payment G-codes could artificially inflate FQHCs’ total gross charges, although others stated that some of the financial discrepancies in payment would be resolved once the FQHC receives payment. However, many commenters stated there would be an administrative burden to a FQHC in the short-term as it attempts to resolve balances and financial statements.

Response: FQHCs may initially have to spend additional time explaining changes in charges and the patient’s EOB, and we encourage them to keep their patients informed of any changes. We also acknowledge that transitioning to a new payment system will require additional time and patience as all aspects of the billing system will need to be adapted.

We noted in the FQHC PPS final rule that although FQHCs set their own charges, FQHCs that receive grant funding under section 330 of the PHS Act are required to maintain charges that are both consistent with locally prevailing rates or charges and are also reflective of their reasonable costs of operation. Therefore, we do not expect that the FQHCs will use the payment G-codes to artificially inflate their charges.

Comment: Several commenters were concerned that the use of G-codes would limit the definition or scope of a qualifying face-to-face visit. Commenters stated that we were limiting the scope of FQHC services by requiring that only certain HCPCS codes support the use of each FQHC payment G-code. Commenters stated that services described by codes other than evaluation and management (E/M) services also meet the definition of a face-to-face visit with a qualifying provider. The commenters recommended that for each qualifying visit, the FQHC should be able to enter the corresponding FQHC payment G-code to be eligible for payment.

Response: We disagree that the new PPS may limit the scope of FQHC

services. All services that qualified as a billable visit under the AIR payment system continue to qualify as a billable visit under the PPS. There has been no change to the scope of services that may be furnished in a FQHC and no change in the type of visits that qualify as a billable visit as a result of the new payment system. Since the previous payment system did not utilize HCPCS coding to determine payment, we anticipate the new payment system will be more transparent, as all services furnished must have the correct HCPCS codes for accurate payment, along with the appropriate G-code for payment. We would also note that in addition to E/M visits, there are many preventive services that can be billed as stand-alone visits in FQHCs under both the AIR and PPS payment systems.

Comment: A few commenters suggested that we develop more G-codes to account for other types of services furnished in a FQHC and G-codes that address varying patient populations. One commenter suggested that we add an additional 10 to 15 HCPCS codes based on the historical claims data for FQHC visits. Another commenter suggested that due to the complex needs of their FQHC patient population, additional FQHC payment G-codes should reflect multiple services, intensity, and cost of furnishing services to their complex patient population.

Response: We stated in the FQHC PPS proposed and final rules that our goal for the FQHC PPS is to implement a system in accordance with the statute whereby FQHCs are fairly paid for the services they furnish to Medicare patients in the least burdensome manner possible, so that they may continue to furnish primary and preventive health services to the communities they serve. In developing the FQHC G-codes, we considered whether there should be fewer G-codes, or more G-codes, than the five that we ultimately proposed. The G-codes are designed to reflect a typical bundle of services that a FQHC furnishes to their Medicare patients, and we determined that having more G-codes would be burdensome without providing any advantage in payment accuracy. However, we will monitor the PPS system and will consider adding additional G-codes if necessary.

Comment: A number of commenters requested clarification that the bundle of services taken into account in the G-code charge reflects the total bundle of services for a FQHC visit, rather than just the services furnished on that day. Some commenters also sought clarification on billing the professional component of a preventive service on a

day subsequent to the day of the visit. These commenters are concerned whether under the new billing requirements for the FQHC PPS all services are meaningfully included in the encounter payment rate even when a component of the service is furnished on a different date than the actual visit.

Response: The FQHC G-codes reflect the services that the FQHC typically furnishes to a Medicare patient that is either a new or established, medical or mental health patient or a patient receiving an IPPE or AWW. This *may* be the same bundle of services that are furnished to the patient on a particular day, but is *not* required to be the same services, as the patient may need more, fewer, or a different set of services on that particular day.

FQHCs may bill for services furnished incident to a visit on the same claim, even if they occur on a different day, as long as the services are furnished in a medically appropriate time frame. For example, if a patient has their blood drawn at the FQHC on a Monday, and sees the FQHC practitioner the following Wednesday, the FQHC would include the venipuncture on the same claim as the visit with the practitioner.

The FQHC G-codes are defined in program instructions in accordance with statutory and regulatory requirements and will be implemented as described.

4. Waiving Coinsurance for Preventive Services When Furnished With Other Services Under the FQHC PPS

In the FQHC PPS proposed rule (78 FR 58386), we proposed that for FQHC claims that include a mix of preventive and non-preventive services, FQHCs would use payments under the PPS to determine the proportional amount of coinsurance that should be waived for payments based on the PPS encounter rate. Since Medicare payment under the FQHC PPS is required to be 80 percent of the lesser of the FQHC's charges or the PPS rate, we proposed that we would continue to use FQHC-reported charges to determine the amount of coinsurance that should be waived for payments based on the FQHC's charge, and that total payment to the FQHC, including both Medicare and beneficiary liability, would not exceed the lesser of the FQHC's charge or the PPS rate.

We acknowledged that our proposed approach for waiving coinsurance for preventive services when furnished with other services was complex and may be difficult for FQHCs to implement, and we invited public comment on how this proposal would impact a FQHC's administrative procedures and billing practices.

Commenters responded that the proposed system to calculate coinsurance was too complex and burdensome and requested that a simplified system be established.

In the final rule referenced above, we agreed with the commenters, and decided to retain the current method used under the AIR system for calculating coinsurance, with certain modifications. Under the new FQHC PPS, the dollar value of the FQHC's reported line-item charge for the preventive service will be subtracted from the full payment amount, whether payment is based on the FQHC's charge or the PPS rate. Medicare will pay the FQHC 100 percent of the dollar value of the FQHC's reported line-item charge for the preventive service, up to the total payment amount. Medicare also will pay a FQHC 80 percent of the remainder of the full payment amount, and beneficiary coinsurance would be assessed at 20 percent of the remainder of the full payment amount. If the reported line-item charge for the preventive service equals or exceeds the full payment amount, Medicare will pay 100 percent of the full payment amount and the beneficiary will not be responsible for any coinsurance.

We believe that this revised methodology is responsive to commenters request for a simpler method of calculating coinsurance and will be more transparent to beneficiaries. We invited comments on this approach to waiving coinsurance for preventive services based on the dollar value of the FQHC's reported line-item charge for preventive services.

We received many comments on how our finalized policy for calculation of coinsurance for preventive services would affect a FQHC's administrative procedures and billing practices. Most commenters appreciated that we are striving for policies that ease administrative burden; however, many of the commenters thought that our revised approach is still too complex and burdensome to implement. The following is a summary of these comments.

Comment: Most commenters supported that we are striving for a waiver of coinsurance calculation that achieves greater simplicity and promotes fair payment under Medicare. A few commenters stated that our revised approach is a common sense and workable approach to applying this important provision. One commenter stated that this approach would allow for FQHCs to assess coinsurance at the time services are furnished, potentially increase rates of collection, and reduce administrative burden. Commenters

who supported the revised approach requested that we closely monitor how the waiver of coinsurance is calculated and determine if further modifications are needed in the future. Most commenters preferred the revised approach, but some expressed concern that it is still too complex and burdensome. Commenters stated that our methodology for the calculation of coinsurance waiver when the services include a mix of preventive and non-preventive services is too complex for the FQHC staff to accurately determine the coinsurance at the time services are furnished. Commenters suggested that FQHCs would be concerned with overcharging the patient and waive all coinsurance when a mixture of preventive and non-preventive services is furnished. Commenters acknowledged that FQHCs could bill the patient after the MAC issues a remittance advice, but the commenters stated that this would increase bad debt. One commenter stated that the revised approach creates an incentive for FQHCs to offer fewer services at each visit and request patients to return on different days for additional services that could have been furnished on the same day.

Response: We appreciate that FQHCs want to accurately determine coinsurance amounts when there is a mix of preventive and non-preventive services furnished on the same day so that beneficiaries are neither overcharged nor undercharged. Since FQHCs set their own charges and develop their own G-codes, they should be able to accurately determine the coinsurance amount. We believe that the proposed method strikes the right balance between accuracy and simplicity, and we will make adjustment as necessary if problems arise. We also note that, under certain circumstances, FQHCs may waive coinsurance amounts for Medicare and Medicaid beneficiaries (see for example, section 1128B(b)(3)(D) of the Act and § 1001.952(k)(2) of the regulations). Also, most FQHCs are subject to the statutory and regulatory requirements of the Health Center Program (section 330 of the PHS Act; 42 CFR Part 51c; and 42 CFR 56.201 through 56.604), which, among other requirements, mandates that they may collect no more than a "nominal fee" from individuals whose annual income is at or below 100 percent of the Federal Poverty Level."

We are not clear why one commenter suggested that the method for calculating coinsurance could create an incentive for FQHCs to offer fewer services at each visit and request patients to return on different days for

additional services that could have been furnished on the same day. However, as we stated in the FQHC PPS final rule, we expect FQHCs to act in the best interests of their patients, which includes scheduling visits in a manner that maximizes the health and safety of their patients.

Comment: Some commenters stated that the complexity of our revised approach does not carry out Congressional intent to provide for complete waiver of coinsurance when covered preventive services are furnished. They stated that when Congress provided for a complete waiver of coinsurance for specific preventive services under section 4104 of the Affordable Care Act, it was intended to improve access to these services, and that requiring Medicare beneficiaries be liable for coinsurance when a mixture of preventive and non-preventive services are furnished does not remove barriers to these services. Commenters also stated that we lack “any specific statutory authorization to waive coinsurance for services provided under the FQHC PPS,” and therefore, CMS is not barred from implementing a complete waiver for coinsurance when a mixture of services are furnished. These commenters stated that a complete waiver of coinsurance for visits involving a preventive service is consistent with the regulation under § 410.152(l), which states that Medicare Part B pays “100 percent of the Medicare payment amount established under the applicable payment methodology for the service setting for providers and suppliers of the following preventive services.” Commenters stated that a FQHC is a provider of such preventive services and that the FQHC PPS is an applicable payment methodology. Commenters surmised that it is more consistent with the regulation to completely waive coinsurance for visits involving a mixture of preventive and non-preventive services rather than implement a partial coinsurance methodology.

Response: We disagree with the commenters’ interpretation that the statutory and regulatory language cited provides us with the authority to waive coinsurance for all services when there is a mix of preventive and non-preventive services furnished during a FQHC encounter. The revised methodology for calculating coinsurance when there is a mix of preventive and non-preventive services on the claim was revised in response to commenters’ concerns that the methodology that was first proposed was overly complex and burdensome.

We believe that the revised methodology is responsive to those concerns, and provides as much simplicity as possible while enabling FQHCs to comply with statutory requirements for the collection of coinsurance.

We are retaining § 405.2410(b)(2)(i), § 405.2410(b)(2)(ii), and § 405.2462(d) of the Medicare regulations as finalized in 79 FR 25475 and will use the current approach to waiving coinsurance for preventive services, whether total payment is based on the FQHC’s charge or the PPS rate, by subtracting the dollar value of the FQHC’s reported line-item charge for the preventive services from the full payment amount.

5. Other Comments

We received many comments requesting that we provide further information through subregulatory guidance to the stakeholder community regarding same-day visits, development of G-code charges, the calculation of coinsurance when a mixture of preventive and non-preventive services are furnished, what is considered the technical and the professional component of preventive services, billing procedures and processing of claims for same-day visits. Several commenters requested specific examples on calculating coinsurance when the claim contains a mixture of preventive and non-preventive services.

Response: The “Medicare Benefit Policy Manual, Chapter 13—Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Services,” and the “Medicare Claims Processing Manual, Chapter 9—Rural Health Clinic (RHC)/Federally Qualified Health Center (FQHC),” are regularly updated and will address these topics. Additional information on the FQHC PPS is available on the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FQHCPPS/index.html>.

We received some comments that were not related to our specific proposals for the FQHC PPS. Although we appreciate the commenters’ feedback on billing for vaccines under Medicare part D, billing for costs relating to language assistance and other enabling services, adjustments to the California GAF, FQHC PPS rate risk adjusters, and the FQHC PPS implementation date, payment for furnishing services to dually eligible Medicare and Medicaid beneficiaries, these topics are beyond the scope of our specific proposals that we specified were subject to public comment in the FQHC PPS.

6. Additional Technical Revisions

a. SNF Consolidated Billing

In this final rule with comment period, we are making a conforming technical revision in § 411.15(p)(2) and § 489.20(s). In the May 2, 2014, interim final rule (79 FR 25462), we updated § 405.2411(b)(2) so that it reflects section 1888(e)(2)(A)(iv) of the Act (as amended by section 410 of the MMA), which excludes certain RHC and FQHC practitioner services from consolidated billing and allows such services to be separately billable under Part B when furnished to a resident of a SNF during a covered Part A stay. This statutory provision was effective with services furnished on or after January 1, 2005 and was previously implemented through program instruction (CMS Pub 100–04, Medicare Claims Processing Manual, Chapter 6, Section 20.1.1).

However, in making this revision, we inadvertently neglected to make a conforming change in § 411.15(p)(2), which enumerates the individual services that are excluded from the SNF consolidated billing provision, as well as in § 489.20(s), which specifies compliance with consolidated billing as a requirement of the SNF’s Medicare provider agreement. Accordingly, we are now rectifying that omission.

Regarding the technical corrections to parts 411 and 489 of the regulations discussed above, we note that we would ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before revisions in the regulations text would take effect; however, we can waive this procedure if we find good cause that a notice and comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporate a statement of the finding and its reasons in the notice issued. We find it unnecessary to undertake notice and comment rulemaking in connection with these particular revisions, as they merely provide technical corrections to the regulations, without making any substantive changes. Therefore, for good cause, we waive notice and comment procedures for the revisions that we are making to the regulations text in parts 411 and 489.

b. Transitional Care Management

In the May 2, 2014 final rule (79 FR 25436), we added transitional care management (TCM) to § 405.2463(a)(1)(ii). To clarify that TCM does not necessarily require a face-to-face visit, we revised this section of the regulation for RHCs, but neglected to add the appropriate reference for

FQHCs. Therefore, we are revising § 405.2463(a)(2)(i), so that a FQHC visit includes a qualified TCM service.

P. Physician Self-Referral Prohibition: Annual Update to the List of CPT/HCPCS Codes

1. General

Section 1877 of the Act prohibits a physician from referring a Medicare beneficiary for certain designated health services (DHS) to an entity with which the physician (or a member of the physician's immediate family) has a financial relationship, unless an exception applies. Section 1877 of the Act also prohibits the DHS entity from submitting claims to Medicare or billing the beneficiary or any other entity for Medicare DHS that are furnished as a result of a prohibited referral.

Section 1877(h)(6) of the Act and § 411.351 of our regulations specify that the following services are DHS:

- Clinical laboratory services
- Physical therapy services
- Occupational therapy services
- Outpatient speech-language pathology services
- Radiology services
- Radiation therapy services and supplies
- Durable medical equipment and supplies
- Parenteral and enteral nutrients, equipment, and supplies
- Prosthetics, orthotics, and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services

2. Annual Update to the Code List

a. Background

In § 411.351, we specify that the entire scope of four DHS categories is defined in a list of CPT/HCPCS codes (the Code List), which is updated annually to account for changes in the most recent CPT and HCPCS Level II publications. The DHS categories defined and updated in this manner are:

- Physical therapy, occupational therapy, and outpatient speech-language pathology services
- Radiology and certain other imaging services
- Radiation therapy services and supplies

The Code List also identifies those items and services that may qualify for either of the following two exceptions to the physician self-referral prohibition:

- EPO and other dialysis-related drugs furnished in or by an ESRD facility (§ 411.355(g))
- Preventive screening tests, immunizations, or vaccines (§ 411.355(h))

The definition of DHS at § 411.351 excludes services that are reimbursed by Medicare as part of a composite rate (unless the services are specifically identified as DHS and are themselves payable through a composite rate, such as home health and inpatient and outpatient hospital services). Effective January 1, 2011, EPO and dialysis-related drugs furnished in or by an ESRD facility (except drugs for which there are no injectable equivalents or other forms of administration), have been reimbursed under a composite rate known as the ESRD prospective payment system (ESRD PPS) (75 FR 49030). Accordingly, EPO and any dialysis-related drugs that are paid for under ESRD PPS are not DHS and are not listed among the drugs that could qualify for the exception at § 411.355(g) for EPO and other dialysis-related drugs furnished by an ESRD facility.

Drugs for which there are no injectable equivalents or other forms of administration were scheduled to be paid under ESRD PPS beginning January 1, 2014 (75 FR 49044). However, on January 3, 2013, Congress enacted the American Taxpayer Relief Act of 2012 (ATRA), (Pub. L. 112–240), which will delay payment of these drugs under ESRD PPS until January 1, 2016. In the meantime, such drugs furnished in or by an ESRD facility are not reimbursed as part of a composite rate and thus, are DHS. For purposes of the exception at § 411.355(g), only those drugs that are

required for the efficacy of dialysis may be identified on the List of CPT/HCPCS Codes as eligible for the exception. As we have explained previously in the CY 2010 PFS final rule (75 FR 73583), we do not believe any of these drugs are required for the efficacy of dialysis. Therefore, we have not included any such drugs on the list of drugs that can qualify for the exception.

The Code List was last updated in Addendum K of the CY 2014 PFS final rule with comment period.

b. Response to Comments

We received no public comments relating to the Code List that became effective January 1, 2014.

c. Revisions Effective for 2015

The updated, comprehensive Code List effective January 1, 2015, is available on our Web site at http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html.

Additions and deletions to the Code List conform it to the most recent publications of CPT and HCPCS Level II, and to changes in Medicare coverage policy and payment status.

Tables 90 and 91 identify the additions and deletions, respectively, to the comprehensive Code List that become effective January 1, 2015. Tables 90 and 91 also identify the additions and deletions to the list of codes used to identify the items and services that may qualify for the exception in § 411.355(g) (regarding dialysis-related outpatient prescription drugs furnished in or by an ESRD facility) and in § 411.355(h) (regarding preventive screening tests, immunizations, and vaccines).

We will consider comments regarding the codes listed in Tables 90 and 91. Comments will be considered if we receive them by the date specified in the **DATES** section of this final rule with comment period. We will not consider any comment that advocates a substantive change to any of the DHS defined in § 411.351.

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TABLE 90: Additions to the Physician Self-Referral List of CPT^{1/}HCPCS Codes

CLINICAL LABORATORY SERVICES
0357T Cryopreservation oocyte(s)
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES
97607 Neg press wnd tx <=50 sq cm
97608 Neg press wound tx >50 cm
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES
76641 Ultrasound breast complete
76642 Ultrasound breast limited
77061 Breast tomosynthesis uni
77062 Breast tomosynthesis bi
77063 Breast tomosynthesis bi
77085 Dxa bone density study
77086 Fracture assessment via dxa
G0279 Tomosynthesis, mammo screen
RADIATION THERAPY SERVICES AND SUPPLIES
A9606 Radium Ra223 dichloride ther
C2644 Brachytx cesium-131 chloride
77306 Telethx isodose plan simple
77307 Telethx isodose plan cplx
77316 Brachytx isodose plan simple
77317 Brachytx isodose intermed
77318 Brachytx isodose complex
77385 Ntsty modul rad tx dlvr smpl
77386 Ntsty modul rad tx dlvr cplx
G6001 Echo guidance radiotherapy
G6002 Stereoscopic x-ray guidance
G6003 Radiation treatment delivery
G6004 Radiation treatment delivery
G6005 Radiation treatment delivery
G6006 Radiation treatment delivery
G6007 Radiation treatment delivery
G6008 Radiation treatment delivery
G6009 Radiation treatment delivery

G6010 Radiation treatment delivery
G6011 Radiation treatment delivery
G6012 Radiation treatment delivery
G6013 Radiation treatment delivery
G6014 Radiation treatment delivery
G6015 Radiation tx delivery imrt
G6016 Delivery comp imrt
G6017 Intrafraction track motion
DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
{No additions}
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES
90630 Flu vacc iiv4 no preserv id
G0464 Colorec CA scr, sto bas DNA

¹CPT codes and descriptions only are copyright 2014 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

TABLE 91: Deletions from the Physician Self-Referral List of CPT¹/HCPCS Codes

CLINICAL LABORATORY SERVICES
0059T Cryopreservation oocyte
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES
{No deletions}
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES
74291 Contrast x-rays gallbladder
76645 Us exam breast(s)
77082 Dxa bone density vert fx
RADIATION THERAPY SERVICES AND SUPPLIES
0073T Delivery comp imrt
0197T Intrafraction track motion
77305 Teletx isodose plan simple
77310 Teletx isodose plan intermed
77315 Teletx isodose plan complex
77326 Brachytx isodose calc simp
77327 Brachytx isodose calc interm
77328 Brachytx isodose plan compl
77403 Radiation treatment delivery
77404 Radiation treatment delivery
77406 Radiation treatment delivery
77408 Radiation treatment delivery
77409 Radiation treatment delivery
77411 Radiation treatment delivery
77413 Radiation treatment delivery
77414 Radiation treatment delivery
77416 Radiation treatment delivery
77418 Radiation tx delivery imrt
77421 Stereoscopic x-ray guidance
G0417 Sat biopsy prostate 21-40
G0418 Sat biopsy prostate 41-60
G0419 Sat biopsy prostate: >60
DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
{No deletions}
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES
{No deletions}

¹ CPT codes and descriptions only are copyright 2014 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

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Q. Interim Final Revisions to the Electronic Health Record (EHR) Incentive Program

1. Statutory Basis

The American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) (ARRA) amended titles XVIII and XIX of the Act to authorize incentive payments to EPs, eligible hospitals, and critical access hospitals (CAHs), and Medicare Advantage (MA) organizations to promote the adoption and meaningful use of CEHRT. Sections 1848(o), 1853(l) and (m), 1886(n), and 1814(l) of the Act provide the statutory basis for the Medicare incentive payments made to meaningful EHR users. These statutory provisions govern EPs, MA organizations (for certain qualifying EPs and hospitals that meaningfully use CEHRT), subsection (d) hospitals, and CAHs, respectively. Sections 1848(a)(7), 1853(l) and (m), 1886(b)(3)(B), and 1814(l) of the Act also establish downward payment adjustments, beginning with calendar or fiscal year 2015, for EPs, MA organizations, subsection (d) hospitals and CAHs that are not meaningful users of CEHRT for certain associated reporting periods. Sections 1903(a)(3)(F) and 1903(t) of the Act provide the statutory basis for Medicaid incentive payments, but do not provide for downward payment adjustments.

Sections 1848(a)(7)(B), 1886(b)(3)(B)(ix)(II), and 1814(l)(4)(C) of the Act provide that the Secretary may, on a case-by-case basis, exempt an EP, eligible hospital, or CAH that is not a meaningful EHR user for an EHR reporting period for the year from the application of the payment adjustment if the Secretary determines that compliance with the requirement for being a meaningful EHR user would result in a significant hardship, such as in the case of an EP, eligible hospital, or CAH that practices or is located in a rural area without sufficient internet access. The exception is subject to annual renewal, but in no case may an exception be granted for more than 5 years.

2. Provisions of the Interim Final Rule With Comment Period

a. Extreme and Uncontrollable Circumstances Hardship Exception

In the September 4, 2014 **Federal Register** (79 FR 52910-52933) CMS and ONC published a final rule titled “Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program for 2014 and

Other Changes to the EHR Incentive Program; and Health Information Technology: Revisions to the Certified EHR Technology Definition and EHR Certification Changes Related to Standards; Final Rule” (“2014 CEHRT Flexibility rule”). The final rule included policies allowing EPs, eligible hospitals, and CAHs that could not fully implement 2014 Edition CEHRT for an EHR reporting period in 2014 due to issues related to 2014 Edition CEHRT availability delays to continue to use 2011 Edition CEHRT or a combination of 2011 Edition and 2014 Edition CEHRT for the EHR reporting periods in CY 2014 and FY 2014, respectively. These CEHRT options applied only to those providers that could not fully implement 2014 Edition CEHRT to meet meaningful use for an EHR reporting period in 2014 due to delays in 2014 Edition CEHRT availability. The final rule also made changes to the attestation process to support these flexible options for CEHRT, although it did not alter the attestation or hardship exception application deadlines for 2014. Therefore, for example, eligible hospitals that never successfully attested to meaningful use prior to FY 2014 were still required to attest by July 1, 2014, and eligible professionals who never successfully attested to meaningful use prior to CY 2014 were required to attest by October 1, 2014, for an EHR reporting period in FY 2014 or CY 2014, respectively, to avoid the Medicare payment adjustments in FY 2015 or CY 2015, respectively. To request a hardship exception from the Medicare payment adjustments in FY or CY 2015, applications were due from eligible professionals by July 1, 2014, eligible hospitals by April 1, 2014, and CAHs by November 30, 2015. In addition, throughout the course of the year, we continued to urge providers to purchase 2014 Edition CEHRT and not wait until the last minute to attest for the EHR reporting period in 2014.

However, following publication of the 2014 CEHRT Flexibility rule, we became aware that providers were confused over their ability to use flexible options provided under the 2014 CEHRT Flexibility rule, especially given the unchanged attestation deadlines. We received numerous letters from various health care associations, multiple questions from stakeholders on provider calls, and numerous emails from providers and EHR vendors, all expressing confusion and seeking clarification about whether they could use the flexible options provided under the 2014 CEHRT Flexibility rule. Specifically, providers were unsure how

they could use the flexible options given that the attestation deadlines for both eligible professionals (October 1, 2014) and eligible hospitals (July 1, 2014) would have occurred on or before the effective date of the 2014 CEHRT Flexibility rule (October 1, 2014). Providers were extremely concerned that their inability to use the flexible options specified in the 2014 CEHRT Flexibility rule would subject them to a payment adjustment in 2015 under Medicare for failing to demonstrate meaningful use of CEHRT. This fear was compounded by the fact that the hardship exception application deadlines for both eligible professionals (July 1, 2014) and eligible hospitals (April 1, 2014) had already passed.

In particular, we became aware that eligible professionals who never successfully attested to meaningful use for the EHR Incentive Program were especially affected by this issue because they would not be able to use the flexibility options outlined in the 2014 CEHRT Flexibility rule before the October 1, 2014 deadline to avoid the payment adjustment in CY 2015, because these options could not be made available in the CMS Registration and Attestation System prior to the October 1, 2014 effective date of the 2014 CEHRT Flexibility rule. We also became aware that eligible professionals also faced uncertainty if they joined practices that were already using 2011 Edition CEHRT and experienced delays in full implementation of 2014 Edition CEHRT. Therefore, we understood that eligible professionals were concerned that the inability to attest by October 1, 2014 using the flexible options under the 2014 CEHRT Flexibility rule would potentially subject them to the payment adjustment in CY 2015 authorized under the Medicare EHR Incentive Program if they could not receive a hardship exception.

Accordingly, to ensure that all providers can use the flexible options recently finalized under the 2014 CEHRT Flexibility rule for an EHR reporting period in 2014, and ensure that providers are not potentially subjected to the 2015 payment adjustment under the Medicare EHR Incentive Program, we are recognizing a hardship exception under the established category of “extreme and uncontrollable circumstances” under 42 CFR § 495.102(d)(4)(iii) for eligible professionals and § 412.64(d)(4)(ii)(B) for eligible hospitals, pursuant to the Secretary’s discretionary hardship exception authority. Under this IFC, we will consider that an extreme and uncontrollable circumstance hardship exists for an eligible professional or

eligible hospital if two criteria are met. First, the provider must not have been able to fully implement the 2014 Edition CEHRT due to delays in 2014 Edition CEHRT availability. Second, the provider must not have been able to attest by their attestation deadline in 2014. For example, for eligible professionals, the eligible professional must not have been able to attest by October 1, 2014 using the flexibility options under the 2014 CEHRT Flexibility rule. For eligible hospitals, the eligible hospital must not have been able to attest by July 1, 2014 using the flexibility options under the 2014 CEHRT Flexibility rule. We will recognize an extreme and uncontrollable circumstance hardship exception under this IFC only for those providers meeting both these criteria and only for the 2015 payment adjustment.

For CAHs, although we would recognize a hardship exception for CAHs under these circumstances, this exception would have little impact on CAHs because the hardship exception application deadline for CAHs for the 2015 payment adjustment does not occur until November 30, 2015. Accordingly, CAHs will have ample time to attest using the flexibility options under the 2014 CEHRT Flexibility rule and will not be impacted in the same manner as eligible hospitals or eligible professionals, whose attestation and hardship exception application deadlines have since passed. However, as explained below, to maximize flexibility in the hardship exception application submission process for all providers under the hardship exception categories, so that we avoid similar situations in the future, like the ones prompting this IFC, we are amending § 413.70(a)(6) to allow CMS the flexibility to specify an alternate hardship exception application submission deadline for certain hardship categories other than November 30th.

b. Extension of Hardship Exception Application Deadline to November 30, 2014 for Eligible Professionals and Eligible Hospitals and Amendments to §§ 495.102, 412.64, and 413.70.

Section 495.102(d)(4) provides the categories of hardship exceptions for EPs, including insufficient internet access, newly practicing EPs, extreme circumstances outside of an EP's control, lack of control over the availability of CEHRT for EPs practicing in multiple locations, lack of face-to-face patient interactions and lack of need for follow-up care, and certain primary specialties. With the exception

of the newly practicing EP hardship exception category, the EP is required to file a hardship exception application to CMS for the remaining hardship categories no later than July 1st of the year before the payment adjustment year.

Similar to eligible professionals, § 412.64(d)(4) provides the categories of hardship exceptions for eligible hospitals, which include insufficient internet access, new eligible hospitals, and extreme and uncontrollable circumstances outside of an eligible hospital's control. Under the hardship exception categories for insufficient internet access and extreme and uncontrollable circumstances, the eligible hospital is required to file a hardship exception application to CMS no later than April 1st of the year before the payment adjustment year.

Similar to eligible hospitals, § 413.70(a)(6) provides the categories of hardship exceptions that CAHs could apply for, which include insufficient internet access, new CAHs, and extreme and uncontrollable circumstances outside of a CAH's control. Under all hardship exception categories, the CAH is required to file a hardship exception application to CMS no later than November 30th after the close of the applicable EHR reporting period for a payment adjustment year to be considered for a hardship exception.

For purposes of the 2015 payment adjustment under the Medicare EHR Incentive Program, the hardship exception application deadlines for both eligible hospitals and eligible professionals have ended. However, we need to accommodate the extreme and uncontrollable circumstance hardship exception recognized under this IFC. Therefore, for purposes of the 2015 payment adjustment under the Medicare EHR Incentive Program, we are extending the hardship exception application submission deadline for both eligible hospitals and eligible professionals to November 30, 2014. We believe that extending the hardship exception application deadline to November 30, 2014 will allow ample time for those eligible hospitals and eligible professionals that could not fully implement 2014 Edition CEHRT due to 2014 Edition CEHRT availability delays and that could not attest by their applicable attestation deadline using the flexibility options provided in the 2014 CEHRT flexibility rule to file an application for the hardship exception recognized under this IFC.

The extension of the hardship exception application submission deadline to November 30, 2014, applies only to those providers who meet the

criteria described under this IFC. We will not extend, reopen, or reconsider the hardship exception application deadline for the 2015 payment adjustment for any other reason. Further, as explained above, because CAHs have still not reached their November 30, 2015 hardship exception application deadline, they are not affected in the same manner as eligible hospitals and eligible professionals, and are still eligible to file a hardship exception application until November 30th under any of the categories specified under § 413.70(a)(6).

Next, to extend the hardship exception application deadline to November 30, 2014, for eligible hospitals and eligible professionals, we must amend under this IFC the July 1st hardship exception application deadline for extreme and uncontrollable circumstances under § 495.102(d)(4)(iii) for eligible professionals and the April 1st deadline under § 412.64(d)(4)(ii)(B) for eligible hospitals. For eligible professionals, the new amendment to § 495.102(d)(4)(iii) will include, following the July 1st hardship exception application submission deadline specified in the regulation, language that would enable CMS to specify a later deadline. For eligible hospitals, the new amendment to § 412.64(d)(4)(ii)(B) will include, following the April 1st hardship exception application submission deadline specified in the regulation, language that would enable CMS to specify a later deadline. We are making these regulatory amendments under this IFC to allow eligible hospitals and eligible professionals to take advantage of the extreme and uncontrollable circumstances hardship exception outlined under this IFC. Without such changes, eligible hospitals and eligible professionals would be unable to apply for this hardship exception because the application deadlines have already passed.

Finally, we note that, as with the circumstances described in this IFC that caused us to extend the deadline to November 30, 2014, there may be situations in the future that would warrant extending the July 1st deadline for eligible professionals, the April 1st deadline for eligible hospitals, and the November 30th deadline for CAHs. Accordingly, to ensure that we do not face similar timing constraints in the future and to reduce administrative burden on providers who wish to request a hardship exception, we are amending the regulation text for the other hardship exception categories to enable CMS to specify a later deadline

for submission of hardship exception applications.

Specifically, for eligible professionals, in addition to the amendments we cited above for § 495.102(d)(4)(iii) relating to the extreme and uncontrollable circumstances hardship exception category, we are also amending § 495.102(d)(4)(i) (insufficient internet access) and (d)(4)(iv) (multiple locations/lack of face-to-face encounters and need for follow-up/certain primary specialties) to add similar language.

For eligible hospitals, in addition to the amendments we cited above for § 412.64(d)(4)(ii)(B) relating to the extreme and uncontrollable circumstances hardship exception category, we are also amending § 412.64(d)(4)(ii)(A) (lack of internet access) to add similar language.

For CAHs, we are amending § 413.70(a)(6)(ii) to add language similar to the language added to the regulation text for eligible professionals and eligible hospitals, as discussed above. We believe that the flexibility to specify a later hardship exception application submission deadline as set forth above will prevent situations such as the one addressed under this IFC where, for example, an unforeseen circumstance occurred, which could justify a hardship exception, but the hardship exception application submission deadline has passed. However, we emphasize that we do not intend to exercise this flexibility to extend the hardship exception application submission deadline frequently. Rather, to maintain the consistency needed for our operations, providers should expect to adhere to the dates specified in the regulation text and not rely on the possibility of changes to the hardship application submission period occurring on a frequent basis.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.

- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Unless noted otherwise, we used data from the U.S. Bureau of Labor Statistics for all salary estimates. The estimates include the cost of fringe benefits, calculated at 35 percent of salary, which is based on the Bureau's June 2012 Employer Costs for Employee Compensation report.

In the CY 2015 PFS proposed rule (79 FR 40317), we solicited public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs).

A. Information Collection Requirements (ICRs)

1. ICRs Regarding the Removal of Employment Requirements for Services Furnished Incident to Rural Health Clinics and Federally Qualified Health Center Visits

This provision removes the requirement that nonphysician RHC or FQHC practitioners be W-2 employees. This action does not require the modification of existing contracts or the creation of new contracts, nor does CMS collect any information on contracting. Consequently, the provision is not subject to the requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

2. ICRs Regarding Access to Identifiable Data for the Center for Medicare and Medicaid Models

This provision concerns the evaluation of models tested under, section 1115A of the Act. Section 1115(A)(d)(3) of the Act provides that the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) shall not apply to the testing, evaluation or expansion of models under section 1115A of the Act.

3. ICRs Regarding Local Coverage Determination Process for Clinical Diagnostic Laboratory Testing

The proposed Clinical Diagnostic Laboratory LCD Process will not be finalized. Consequently, the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and the LCD process do not apply to this final rule.

4. ICRs Regarding the Solicitation of Comments on the Payment Policy for Substitute Physician Billing Arrangements

The proposed rule solicited comment on substitute billing arrangements and did not set out any new or revised

collection of information requirements. Consequently, the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) is not applicable.

5. ICRs Regarding Reports of Payments or Other Transfers of Value and Physician Ownership and Investment Interests (§ 403.904(c)(8), (d)(3), and (g))

With regard to the following provisions, no PRA-related comments were received. The proposed provisions are being adopted without change.

In § 403.904(c)(8), applicable manufacturers and applicable group purchasing organizations (GPOs) must report the marketed name and therapeutic area or product category of covered drugs, devices, biologicals and medical supplies. The amendment has non-measurable effect on current burden estimates since the manufacturers and GPOs are already required to report the marketed name for drugs and biologicals and report the marketed name, therapeutic area, or product category for devices and medical supplies. While the requirement has no burden implications, the provision will be submitted to OMB for approval under control number 0938-1173 (CMS-10419).

In § 403.904(d)(3), applicable manufacturers and applicable GPOs must report the form of payment or other transfers of value as: Cash or cash equivalent, in-kind items or services, stock, stock option, or any other ownership investment. The burden associated with this provision is the time and effort it will take each applicable manufacturer and applicable GPO to revise their reporting system to report the form of payment.

The removal of § 403.904(g) requires that applicable manufacturers and applicable GPOs of covered drugs, devices, biologicals, and medical supplies report annually to CMS all payments or other transfers of value provided as compensation for speaking at a continuing education program. The ongoing burden associated with this provision is the time and effort it will take each applicable manufacturer and applicable GPO to report payments or other transfers of value to CMS which were provided to physicians at a continuing education program. We estimate that it will take 1.0 hour to report payments or other transfers of value to CMS which were provided to physician at a continuing education program.

We estimate that it will take 1.0 hour to report payments or other transfers of value to CMS which were provided to physician covered recipients as

compensation for speaking at a continuing education program and 0.5 hours to revise an applicable manufacturer or applicable GPO's reporting system to report the form of payment.

In deriving these figures, we used the following hourly labor rates and estimated the time to complete each task: \$26.39/hr and 1.0 hours for support staff to report payments or other transfers of value to CMS which were provided to physician covered recipients as compensation for speaking at a continuing education program and \$4+7.55/hr and 0.5 hours for support to revise their reporting system to report the form of payment.

The preceding requirements and burden estimates will be added to the existing PRA-related requirements and burden estimates that have been approved by OMB under control number 0938-1173 (CMS-10419).

6. ICRs Regarding Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System

With regard to the following provisions, no PRA-related comments were received. The proposed provisions are being adopted without change.

The annual burden estimate is calculated separately for the 2017 PQRS payment adjustment (the reporting periods of which occur in 2015): (1) Individual eligible professionals and group practices using the claims (for eligible professionals only), (2) qualified registry and QCDR, (3) EHR-based reporting mechanisms, and (4) group practices using the group practice reporting option (GPRO). Please note that we are grouping group practices using the qualified registry and EHR-based reporting mechanisms with the burden estimate for individual eligible professionals using the qualified registry and EHR-based reporting mechanisms because we believe the criteria for satisfactory reporting for group practices using these 2 reporting mechanisms under the GPRO are similar to the satisfactory reporting criteria for eligible professionals using these reporting mechanisms.

a. Burden Estimate for PQRS Reporting by Individual Eligible Professionals: Reporting in General

According to the 2012 Reporting Experience, "more than 1.2 million eligible professionals were eligible to participate in the 2012 PQRS, Medicare Shared Savings Program, and Pioneer ACO Model."³¹ In this burden estimate,

we assume that 1.2 million eligible professionals, the same number of eligible professionals eligible to participate in the PQRS in 2012, will be eligible to participate in the PQRS. Historically, the PQRS has never experienced 100 percent participation in reporting for the PQRS. Therefore, we believe that although 1.2 million eligible professionals will be subject to the 2017 PQRS payment adjustment, not all eligible participants will report quality measures data for purposes of the 2017 PQRS payment adjustment. In this burden estimate, we will only provide burden estimates for the eligible professionals and group practices who attempt to submit quality measures data for purposes of the 2017 PQRS payment adjustment.

In 2012, 435,871 eligible professionals (36 percent of eligible professionals, including those who belonged to group practices that reported under the GPRO and eligible professionals within an ACO that participated in the PQRS via the Shared Savings Program or Pioneer ACO model) participated in the PQRS, Medicare Shared Savings Program, or Pioneer ACO Model.³² We expect to see a significant increase in participation in reporting for the PQRS in 2015 than 2012 as eligible professionals were not subject to a PQRS payment adjustment in 2012. Last year, we estimated that we would see a 50 percent participation rate in 2015. We still believe that a 14 percent increase in participation from 2012 is reasonable in 2015. Therefore, we estimate that 50 percent of eligible professionals (or approximately 600,000 eligible professionals) will report quality measures data for purposes of the 2017 PQRS payment adjustment.

With respect to the PQRS, the burden associated with the requirements of this voluntary reporting initiative is the time and effort associated with individual eligible professionals identifying applicable quality measures for which they can report the necessary information, selecting a reporting option, and reporting the information on their selected measures or measures group to CMS using their selected reporting option.

We believe the labor associated with eligible professionals and group practices reporting quality measures data in the PQRS is primarily handled by an eligible professional's or group practice's billing clerk or computer analyst trained to report quality measures data. Therefore, we will

consider the hourly wage of a billing clerk and computer analyst in our estimates. For purposes of this burden estimate, we assume that a billing clerk will handle the administrative duties associated with participating in the PQRS. According to information published by the Bureau of Labor Statistics, available at <http://www.bls.gov/oes/current/oes433021.htm>, the mean hourly wage for a billing clerk is approximately \$32.00/hour. Therefore, for purposes of handling administrative duties, we estimate an average labor cost of \$32.00/hour. In addition, for purposes of this burden estimate, we assume that a computer analyst will engage in the duties associated with the reporting of quality measures. According to information published by the Bureau of Labor Statistics, available at <http://www.bls.gov/oes/current/oes151121.htm>, the mean hourly wage for a computer analyst is approximately \$82.00/hour. Therefore, for purposes of reporting on quality measures, we estimate an average labor cost of \$82.00/hour.

Please note that, in assessing PQRS-specific burden estimates, to account for benefits and overhead associated with labor in addition to the hourly wage costs described above, we are doubling the wage rates in our estimates. While we accounted for fringe benefits in the NPRM's wage estimates, we did not double the wage rates in those estimates.

For individual eligible professionals, the burden associated with the requirements of this reporting initiative is the time and effort associated with eligible professionals identifying applicable quality measures for which they can report the necessary information, collecting the necessary information, and reporting the information needed to report the eligible professional's measures. We believe it is difficult to accurately quantify the burden because eligible professionals may have different processes for integrating the PQRS into their practice's work flows. Moreover, the time needed for an eligible professional to review the quality measures and other information, select measures applicable to his or her patients and the services he or she furnishes to them, and incorporate the use of quality data codes into the office work flows is expected to vary along with the number of measures that are potentially applicable to a given professional's practice. Since eligible professionals are generally required to report on at least 9 measures covering at least 3 National Quality Strategy domains criteria for

³¹ Centers for Medicare and Medicaid Services, *2012 Reporting Experience Including Trends (2007–*

2013): Physician Quality Reporting System and Electronic Prescribing (eRx) Incentive Program, March 14, 2014, at xiii.

³² Id. at XV.

satisfactory reporting (or, in lieu of satisfactory reporting, satisfactory participation in a QCDR) for the 2017 PQRS payment adjustment, we assume that each eligible professional reports on an average of 9 measures for this burden analysis.

For eligible professionals who are participating in PQRS for the first time, we will assign 5 total hours as the amount of time needed for an eligible professional's billing clerk to review the PQRS measures list, review the various reporting options, select the most appropriate reporting option, identify the applicable measures or measures groups for which they can report the necessary information, review the measure specifications for the selected measures or measures groups, and incorporate reporting of the selected measures or measures groups into the office work flows. The measures list contains the measure title and brief summary information for the eligible professional to review. Assuming the eligible professional has received no training from his/her specialty society, we estimate it will take an eligible professional's billing clerk up to 2 hours to review this list, review the reporting options, and select a reporting option and measures on which to report. If an eligible professional has received training, then we believe this would take less time. CMS believes 3 hours is plenty of time for an eligible professional to review the measure specifications of 9 measures or 1 measures group they select to report for purposes of participating in PQRS and to develop a mechanism for incorporating reporting of the selected measures or measures group into the office work flows. Therefore, we believe that the start-up cost for an eligible professional to report PQRS quality measures data is 5 hours \times \$32/hour = \$160.

We continue to expect the ongoing costs associated with PQRS participation to decline based on an eligible professional's familiarity with and understanding of the PQRS, experience with participating in the PQRS, and increased efforts by CMS and stakeholders to disseminate useful educational resources and best practices.

We believe the burden associated with reporting the quality measures will vary depending on the reporting mechanism selected by the eligible professional. As such, we break down the burden estimates by eligible professionals and group practices participating in the GPRO according to the reporting mechanism used.

b. Burden Estimate for PQRS Reporting by Individual Eligible Professionals and Group Practices: Claims-Based Reporting Mechanism

According to the 2011 PQRS and eRx Experience Report, in 2011, 229,282 of the 320,422 eligible professionals (or 72 percent) of eligible professionals used the claims-based reporting mechanism. According to the 2012 Reporting Experience, 248,206 eligible professionals participated in the PQRS using the claims-based reporting mechanism in 2012.³³ Preliminary estimates show that 252,567 eligible professionals participated in the PQRS using the claims-based reporting mechanism in 2013.³⁴

According to the historical data cited above, while the claims-based reporting mechanism is still the most widely-used reporting mechanism, we are seeing a decline in the use of the claims-based reporting mechanism in the PQRS. While these eligible professionals continue to participate in the PQRS, these eligible professionals have started to shift towards the use of other reporting mechanisms—mainly the GPRO Web interface (whether used by a PQRS GPRO or an ACO participating in the PQRS via the Medicare Shared Savings Program or the Pioneer ACO Model), registry, or the EHR-based reporting mechanisms. For purposes of this burden estimate, based on PQRS participation using the claims-based reporting mechanism in 2012 and 2013, we assume that approximately 250,000 eligible professionals will participate in the PQRS using the claims-based reporting mechanism.

For the claims based reporting option, eligible professionals must gather the required information, select the appropriate quality data codes (QDCs), and include the appropriate QDCs on the claims they submit for payment. The PQRS will collect QDCs as additional (optional) line items on the existing HIPAA transaction 837 P and/or CMS form CMS-1500 (OMB control number 0938-0999). We do not anticipate any new forms and/or any modifications to the existing transaction or form. We also do not anticipate changes to the 837 P or CMS-1500 for CY 2015.

We estimate the cost for an eligible professional to review the list of quality measures or measures groups, identify the applicable measures or measures groups for which they can report the necessary information, incorporate reporting of the selected measures into the office work flows, and select a PQRS

reporting option to be approximately \$410 per eligible professional (\$82 per hour \times 5 hours).

Based on our experience with the Physician Voluntary Reporting Program (PVRP), we continue to estimate that the time needed to perform all the steps necessary to report each measure (that is, reporting the relevant quality data code(s) for 9 measures measure) would range from 15 seconds (0.25 minutes) to over 12 minutes for complicated cases and/or measures, with the median time being 1.75 minutes. To report 9 measures, we estimate that it will take approximately 2.25 minutes to 108 minutes to perform all of the necessary reporting steps.

Per measure, at an average labor cost of \$82/hour per practice, the cost associated with this burden will range from \$0.34 to about \$16.40 for more complicated cases and/or measures, with the cost for the median practice being \$2.40. To report 9 measures, using an average labor cost of \$82/hour, we estimated that the cost of reporting for an eligible professional via claims will range from \$3.07 (2.25 minutes or 0.0375 hours \times \$82/hour) to \$147.60 (108 minutes or 1.8 hours \times \$82/hour) per reported case.

The total estimated annual burden for this requirement will also vary along with the volume of claims on which quality data is reported. In previous years, when we required reporting on 80 percent of eligible cases for claims based reporting, we found that on average, the median number of reporting instances for each of the PQRS measures was 9. Since we reduced the required reporting rate by over one-third to 50 percent, then for purposes of this burden analysis we assume that an eligible professional or eligible professional in a group practice will need to report each selected measure for 6 reporting instances. The actual number of cases on which an eligible professional or group practice is required to report quality measures data will vary, however, with the eligible professional's or group practice's patient population and the types of measures on which the eligible professional or group practice chooses to report (each measure's specifications includes a required reporting frequency).

Based on these assumptions, we estimate that the total annual reporting burden per individual eligible professional associated with claims based reporting will range from 13.5 minutes (0.25 minutes per measure \times 9 measures \times 6 cases per measure) to 648 minutes (12 minutes per measure \times 9 measures \times 6 cases per measure), with the burden to the median practice being

³³ *Id.* at xvi. See Figure 4.

³⁴ *Id.*

94.5 minutes (1.75 minutes per measure \times 9 measures \times 6 cases). We estimate the total annual reporting cost per eligible professional or eligible professional in a group practice associated with claims based reporting will range from \$18.36 (\$0.34 per measure \times 9 measures \times 6 cases per measure) to \$885.60 (\$16.40 per measure \times 9 measures \times 6 cases per measure), with the cost to the median practice being \$129.60 per eligible professional (\$2.40 per measure \times 9 measures \times 6 cases per measure).

c. Burden Estimate for PQRS Reporting by Individual Eligible Professionals and Group Practices: Qualified Registry-Based and QCDR-Based Reporting Mechanisms

In 2011, approximately 50,215 (or 16 percent) of the 320,422 eligible professionals participating in PQRS used the qualified registry-based reporting mechanism. According to the 2012 Reporting Experience, 36,473 eligible professionals reported individual measures via the registry-based reporting mechanism, and 10,478 eligible professionals reporting measures groups via the registry-based reporting mechanism in 2012.³⁵ Therefore, approximately 47,000 eligible professionals participated in the PQRS using the registry-based reporting mechanism in 2012. Please note that we currently have no data on participation in the PQRS via a QCDR as 2014 is the first year in which an eligible professional may participate in the PQRS via a QCDR.

We believe that the rest of the eligible professionals not participating in other PQRS reporting mechanisms will use either the registry or QCDR reporting mechanisms for the following reasons:

- The PQRS measures set is moving away from use of claims-based measures and moving towards the use of registry-based measures.
- We believe the number of QCDR vendors will increase as the QCDR reporting mechanism evolves.

Therefore, based on these assumptions, we expect to see a significant jump from 47,000 eligible professionals to approximately 165,000 eligible professionals using either the registry-based reporting mechanism or QCDR in 2015. We believe the majority of these eligible professionals will participate in the PQRS using a QCDR, as we presume QCDRs will be larger entities with more members.

For qualified registry based and QCDR-based reporting, there will be no additional time burden for eligible professionals or group practices to

report data to a qualified registry as eligible professionals and group practices opting for qualified registry based reporting or use of a QCDR will more than likely already be reporting data to the qualified registry for other purposes and the qualified registry will merely be repackaging the data for use in the PQRS. Little, if any, additional data will need to be reported to the qualified registry or QCDR solely for purposes of participation in the PQRS. However, eligible professionals and group practices will need to authorize or instruct the qualified registry or QCDR to submit quality measures results and numerator and denominator data on quality measures to CMS on their behalf. We estimate that the time and effort associated with this will be approximately 5 minutes per eligible professional or eligible professional within a group practice.

Please note that, unlike the claims-based reporting mechanism that would require an eligible professional to report data to CMS on quality measures on multiple occasions, an eligible professional would not be required to submit this data to CMS, as the qualified registry or QCDR would perform this function on the eligible professional's behalf.

d. Burden Estimate for PQRS Reporting by Individual Eligible Professionals and Group Practices: EHR-Based Reporting Mechanism

According to the 2011 PQRS and eRx Experience Report, in 2011, 560 (or less than 1 percent) of the 320,422 eligible professionals participating in PQRS used the EHR-based reporting mechanism. In 2012 there was a sharp increase in reporting via the EHR-based reporting mechanism. Specifically, according to the 2012 Reporting Experience, in 2012, 19,817 eligible professionals submitted quality data for the PQRS through a qualified EHR.³⁶

We believe the number of eligible professionals and group practices using the EHR-based reporting mechanism will steadily increase as eligible professionals become more familiar with EHR products and more eligible professionals participate in programs encouraging the use of an EHR, such as the EHR Incentive Program. In particular, we believe eligible professionals will transition from using the claims-based to the EHR-based reporting mechanism. To account for this anticipated increase, we continue to estimate that approximately 50,000 eligible professionals, whether participating as an individual or part of

a group practice under the GPRO, would use the EHR-based reporting mechanism in CY 2015.

For EHR-based reporting, which includes EHR reporting via a direct EHR product and an EHR data submission vendor's product, the eligible professional or group practice must review the quality measures on which we will be accepting PQRS data extracted from EHRs, select the appropriate quality measures, extract the necessary clinical data from his or her EHR, and submit the necessary data to the CMS-designated clinical data warehouse.

For EHR based reporting for the PQRS, the individual eligible professional or group practice may either submit the quality measures data directly to CMS from their EHR or utilize an EHR data submission vendor to submit the data to CMS on the eligible professional's or group practice's behalf. To submit data to CMS directly from their EHR, the eligible professional or eligible professional in a group practice must have access to a CMS specified identity management system, such as IACS, which we believe takes less than 1 hour to obtain. Once an eligible professional or eligible professional in a group practice has an account for this CMS specified identity management system, he or she will need to extract the necessary clinical data from his or her EHR, and submit the necessary data to the CMS designated clinical data warehouse. With respect to submitting the actual data file for the respective reporting period, we believe that this will take an eligible professional or group practice no more than 2 hours, depending on the number of patients on which the eligible professional or group practice is submitting. We believe that once the EHR is programmed by the vendor to allow data submission to CMS, the burden to the eligible professional or group practice associated with submission of data on quality measures should be minimal as all of the information required to report the measure should already reside in the eligible professional's or group practice's EHR.

e. Burden Estimate for PQRS Reporting by Group Practices Using the GPRO Web Interface

As we noted in last year's estimate, according to the 2011 Experience Report, approximately 200 group practices participated in the GPRO in 2011. According to the 2012 Reporting Experience, 66 practices participated in

³⁵ *Id.* at xvi. See Figure 4.

³⁶ *Id.* at xv.

the PQRS GPRO.³⁷ In addition, 144 ACOs participated in the PQRS GPRO through either the Medicare Shared Savings Program (112 ACOs) or Pioneer ACO Model (32 practices).³⁸ These group practices encompass 134,510 eligible professionals (or approximately 140,000 eligible professionals).³⁹ Since it seems that roughly 200 group practices participated in the GPRO in 2011 and 2012, based on these numbers, we assume that 200 group practices (accounting for approximately 135,000 eligible professionals) will participate in the PQRS using the GPRO web interface in 2015.

With respect to the process for group practices to be treated as satisfactorily submitting quality measures data under the PQRS, group practices interested in participating in the PQRS through the GPRO must complete a self-nomination process similar to the self-nomination process required of qualified registries. However, since a group practice using the GPRO web interface would not need to determine which measures to report under PQRS, we believe that the self-nomination process is handled by a group practice's administrative staff. Therefore, we estimate that the self-nomination process for the group practices for the PQRS involves approximately 2 hours per group practice to review the PQRS GPRO and make the decision to participate as a group rather than individually and an additional 2 hours per group practice to draft the letter of intent for self-nomination, gather the requested TIN and NPI information, and provide this requested information. It is estimated that each self-nominated entity will also spend 2 hours undergoing the vetting process with CMS officials. We assume that the group practice staff involved in the group practice self-nomination

process has an average practice labor cost of \$32 per hour. Therefore, assuming the total burden hours per group practice associated with the group practice self-nomination process is 6 hours, we estimate the total cost to a group practice associated with the group practice self-nomination process to be approximately \$192 ($\$32 \text{ per hour} \times 6 \text{ hours per group practice}$).

The burden associated with the group practice reporting requirements under the GPRO is the time and effort associated with the group practice submitting the quality measures data. For physician group practices, this would be the time associated with the physician group completing the web interface. We estimate that the time and effort associated with using the GPRO web interface will be comparable to the time and effort associated to using the PAT. As stated above, the information collection components of the PAT have been reviewed by OMB and are approved under control number 0938–0941 (form CMS–10136) with an expiration date of July 31, 2015, for use in the PGP, MCMP, and EHR demonstrations. As the GPRO was only recently implemented in 2010, it is difficult to determine the time and effort associated with the group practice submitting the quality measures data. As such, we will use the same burden estimate for group practices participating in the GPRO as we use for group practices participating in the PGP, MCMP, and EHR demonstrations. Since these changes will not have any impact on the information collection requirements associated with the PAT and we will be using the same data submission process used in the PGP demonstration, we estimate that the burden associated with a group practice completing data for PQRS under the web interface will be the same as for the group practice to complete the PAT for the PGP demonstration. In other words,

we estimate that, on average, it will take each group practice 79 hours to submit quality measures data via the GPRO web interface at a cost of \$82 per hour. Therefore, the total estimated annual cost per group practice is estimated to be approximately \$6,478.

7. ICRs Regarding the Medicare Shared Savings Program

Section 3022 of the Affordable Care Act exempts any collection of information associated with the Medicare Shared Savings Program from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

8. ICRs Regarding Interim Revisions to the Electronic Health Record (EHR) Incentive Program

This rule does not impose new or alter existing reporting, recordkeeping, or third-party disclosure requirements. Consequently, it need not be reviewed by OMB under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

9. ICRs Regarding the Extreme and Uncontrollable Circumstances Hardship Exception

With regard to the hardship application, this rule will not impose any new or revised reporting, recordkeeping, or third-party disclosure requirements and therefore, does not require additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The application's information collection requirements and burden have been approved by OMB under OMB control number 0938–1158 (CMS–10336).

B. Summary of Final Burden Estimates

Table 92 summarizes this rule's requirements and burden estimates.

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³⁷ *Id.* at xv.

³⁸ *Id.* at xvi.

³⁹ *Id.* at 18.

TABLE 92: Annual Recordkeeping and Reporting Requirements and Burden

Regulation Section(s)	OMB & CMS ID #s	Respondents	Responses (total)	Burden (time) per Response	Total Annual Burden (hours)	Labor Cost of Reporting (\$/hr)	Total Cost (\$)
403.904(d)(3)	0938-1173 (CMS-10419)	1,150 (manufacturers)	1,150	1.0 hr (reporting)	1,150	26.39	30,349
				0.5 hr (system upgrades)	575	47.55	27,341
		420 (GPOs)	420	1.0 hr (reporting)	420	26.39	11,084
				0.5 hr (system upgrades)	210	47.55	9,986
CY 2015 PQRS (start up for first time participants)	0938-1059 (CMS-10276)	164,000	164,000	5 hr	820,000	16.00	13,120,000
CY 2015 PQRS (Claims-Based Reporting Mechanism)	0938-1059 (CMS-10276)	250,000	250,000 (preparation and reporting)	5.2241	1,306,025	82.00	107,090,000
CY 2015 PQRS (Qualified Registry-based and QCDR-based Reporting Mechanisms)	0938-1059 (CMS-10276)	165,000	165,000	5 min	13,750	N/A*	N/A
CY 2015 PQRS (EHR-Based Reporting Mechanism)	0938-1059 (CMS-10276)	50,000	50,000	N/A**	N/A	N/A	N/A
CY 2015 PQRS (Group Practices Using the GPRO Web Interface)	0938-1059 (CMS-10276)	200	200 (self-nomination process)	6 hr	17,000	192.00	1,334,000
			200 (reporting)	79 hr			
TOTAL		630,770	14,130,970	--	2,159,130	--	121,622,760

*There is no set cost. As explained above, the cost will vary depending on the registry used. Additionally, many EPs and group practices using a registry or QCDR will most likely use a registry or QCDR for other purposes.

**As explained above, the burden associated with the submission of data is minimal.

To obtain copies of the supporting statement and any related forms for the paperwork collections referenced above, access CMS' Web site at <http://www.cms.hhs.gov/>

PaperworkReductionActof1995; email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov; or call the Reports Clearance Office at 410-786-1326.

When commenting on the stated information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

Mail: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax: (202) 395-5806 OR, Email: OIRA_submission@omb.eop.gov.

PRA-specific comments must be received by December 1, 2014.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Waiver of Proposed Rulemaking and Waiver of Delay in Effective Date

A. PFS provisions

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We utilize HCPCS codes for Medicare payment purposes. The HCPCS is a national coding system comprised of Level I (CPT) codes and Level II (HCPCS National Codes) that are intended to provide uniformity to coding procedures, services, and supplies across all types of medical providers and suppliers. Level I (CPT) codes are copyrighted by the AMA and consist of

several categories, including Category I codes which are 5-digit numeric codes, and Category III codes which are temporary codes to track emerging technology, services, and procedures.

The AMA issues an annual update of the CPT code set each Fall, with January 1 as the effective date for implementing the updated CPT codes. The HCPCS, including both Level I and Level II codes, is similarly updated annually on a CY basis. Annual coding changes are not available to the public until the Fall immediately preceding the annual January update of the PFS. Because of the timing of the release of these new and revised codes, it is impracticable for us to provide prior notice and solicit comment on these codes and the RVUs assigned to them in advance of publication of the final rule that implements the PFS. Yet, it is imperative that these coding changes be accounted for and recognized timely under the PFS for payment because services represented by these codes will be furnished to Medicare beneficiaries by physicians and practitioners during the CY in which they become effective. Moreover, regulations implementing HIPAA (42 CFR parts 160 and 162) require that the HCPCS be used to report health care services, including services paid under the PFS. We assign interim RVUs to any new and revised codes based on a review of the RUC recommendations for valuing these services. We also assign interim RVUs to certain codes for which we did not receive specific RUC recommendations, but that are components of new combined codes. We set interim RVUs for the component codes in order to conform them to the value of the combined code. Finally, we assign interim RVUs to certain codes for which we received RUC recommendations for only one component (work or PE) but not both. By reviewing these RUC recommendations for the new and revised codes, we are able to assign RVUs to services based on input from the medical community and to establish payment for them, on an interim basis, that corresponds to the relative resources associated with furnishing the services. We are also able to determine, on an interim final basis, whether the codes will be subject to other payment policies. If we did not assign RVUs to new and revised codes on an interim basis, the alternative would be to either not pay for these services during the initial CY or have each Medicare contractor establish a payment rate for these new codes. We believe both of these alternatives are contrary to the public interest, particularly since the

RUC process allows for an assessment of the valuation of these services by the medical community prior to our establishing payment for these codes on an interim basis. Therefore, we believe it would be contrary to the public interest to delay establishment of fee schedule payment amounts for these codes until notice and comment procedures could be completed.

This final rule with comment period revises the process we will use to address new, revised in order to minimize the need to establish RVUs on an interim final basis beginning with rulemaking for CY 2017. However, for the reasons previously outlined in this section, we find good cause to waive the notice of proposed rulemaking for the interim RVUs for selected procedure codes identified in Addendum C and to establish RVUs for these codes on an interim final basis for CY 2015. We are providing a 60-day public comment period.

Section II.E. of this final rule with comment period discusses our review and decisions regarding the RUC recommendations. Similar to the RUC recommendations for new and revised codes previously discussed, due to the timing of the RUC recommendations for the services identified as potentially misvalued codes, it is impracticable for CMS to provide for notice and comment regarding specific revisions prior to publication of this final rule with comment period. We believe it is in the public interest to implement the revised RVUs for the codes that were identified as misvalued, and that have been reviewed and re-evaluated by the RUC, on an interim final basis for CY 2015. The revised RVUs for these codes will establish a more appropriate payment that better corresponds to the relative resources involved in furnishing these services. A delay in implementing revised values for these misvalued codes would not only perpetuate the known misvaluation for these services, it would also perpetuate distortion in the payment for other services under the PFS. Implementing the changes on an interim basis allows for a more equitable resource-based distribution of payments across all PFS services. We believe a delay in implementation of these revisions would be contrary to the public interest, particularly since the RUC process allows for an assessment of the valuation of these services by the medical community prior to the RUC's recommendation to CMS. This final rule with comment period revises the process we will use to address misvalued codes in order to minimize the need to establish RVUs on an interim final basis beginning with

rulemaking for CY 2017. However, for the reasons previously described, we find good cause to waive notice and comment procedures with respect to the misvalued codes and to revise RVUs for these codes on an interim final basis for CY 2015. We are providing a 60-day public comment period.

B. FQHC PPS Rates and Adjustments

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule before publishing a final rule that responds to comments and sets forth final regulations that generally take effect at least 30 days later. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

In the May 2, 2014, interim final rule (79 FR 25462), we updated § 405.2411(b)(2) so that it reflects section 1888(e)(2)(A)(iv) of the Act (as amended by section 410 of the MMA), which excludes certain RHC and FQHC practitioner services from consolidated billing and allows such services to be separately billable under Part B when furnished to a resident of a SNF during a covered Part A stay.

However, in making this revision, we inadvertently neglected to make a conforming change in § 411.15(p)(2), which enumerates the individual services that are excluded from the SNF consolidated billing provision, as well as in § 489.20(s), which specifies compliance with consolidated billing as a requirement of the SNF's Medicare provider agreement. Accordingly, we are now rectifying that omission in this final rule with comment period, by making a conforming technical revision in § 411.15(p)(2) and § 489.20(s).

These particular revisions merely provide technical corrections to the regulations, without making any substantive changes. Therefore, for good cause, we waive notice and comment procedures for the revisions to the regulations text in parts 411 and 489.

C. Interim Final Revisions to the Electronic Health Record (EHR) Incentive Program

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and

issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

With regard to the interim revisions to the Electronic Health Record (EHR) Incentive Program, we find good cause to waive the notice-and-comment procedure as contrary to the public interest. We believe that providing notice and a comment period would prevent us from providing relief from the circumstances outlined in section III.Q. A delay would interfere with the ability of eligible professionals and eligible hospitals to request a hardship exception for the extreme and uncontrollable circumstances specified under this IFC given that the hardship applications deadlines have since passed for both eligible professionals and eligible hospitals. Any delay to this IFC would potentially subject providers to the 2015 payment adjustment under the Medicare EHR Incentive Program and potentially decrease participation in the EHR Incentive Programs, thereby creating a negative impact to the forward movement of the EHR Incentive Programs. For these reasons, we find good cause to waive the notice of proposed rulemaking for these revisions to the EHR Incentive Program and to establish these revisions on an interim final basis. We are providing a 60-day public comment period.

We ordinarily provide a 60-day delay in the effective date of final rules after the date they are issued. The 60-day delay in effective date can be waived, however, if the agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued. The delayed effective date may also be waived in the case of a substantive rule which grants or recognizes an exemption or relieves a restriction. For the reasons set forth below, we believe it would be contrary to the public interest to delay the effective date of the interim final revisions to the EHR Incentive Program described in section III.Q of this final rule with comment period. We also believe these interim final revisions relieve a restriction.

The IFC recognizes a hardship exception based on extreme and uncontrollable circumstances, which could potentially provide relief from the application of the 2015 payment adjustment under the Medicare EHR Incentive Program to certain providers.

This IFC would also relieve a restriction by amending the existing deadlines in the regulation text for providers to apply for hardship exceptions from the payment adjustments. Unless these amendments to the deadlines are made effective immediately, eligible hospitals and eligible professionals would not have enough time to take advantage of the November 30th extended hardship exception application submission period specified in this IFC, given that their hardship exception application submission deadlines have since passed. We find good cause to waive the delayed effective date of the interim final revisions to the EHR Incentive Program and find that they relieve an existing restriction by changing the deadlines by which providers must apply for hardship exceptions. These provisions will be effective on October 31, 2014.

VI. Regulatory Impact Analysis

A. Statement of Need

This final rule with comment period is necessary to make payment and policy changes under the Medicare PFS and to make required statutory changes under the Pathway for SGR Reform Act of 2013 and the PAMA. This final rule with comment period also is necessary to make changes to Part B payment policy for clinical diagnostic lab tests and other Part B related policies. This rule also implements aspects of the data collection required under section 1115A(b)(4) of the Act.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2013), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects

(\$100 million or more in any 1 year). We estimate, as discussed below in this section, that the PFS provisions included in this final rule with comment period will redistribute more than \$100 million in 1 year. Therefore, we estimate that this rulemaking is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details see the SBA’s Web site at <http://www.sba.gov/content/table-small-business-size-standards> (refer to the 620000 series)). Individuals and States are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other providers and suppliers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section as well as elsewhere in this final rule with comment period is intended to comply with the RFA requirements.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small

rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule with comment period would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on State, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately \$141 million. This final rule with comment period would impose no mandates on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

We have prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this final rule with comment period; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we would use to minimize the burden on small entities. As indicated elsewhere in this final rule with comment period, we are implementing a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services, and to implement statutory provisions. We provide information for each of the policy changes in the relevant sections of this final rule with comment period. We are unaware of any relevant federal rules that duplicate, overlap, or conflict with this final rule with comment period. The relevant sections of this final rule with comment period contain a description of significant alternatives if applicable.

C. Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and Malpractice RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than \$20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare revenues for PFS services compare payment rates for CY 2014 with payment rates for CY 2015 using CY 2013 Medicare utilization as the basis for the comparison. The payment impacts reflect averages for each specialty based on Medicare utilization. The payment impact for an individual physician could vary from the average and would depend on the mix of services the physician furnishes. The average change in total revenues would be less than the impact displayed here because physicians furnish services to both Medicare and non-Medicare patients and specialties may receive substantial Medicare revenues for services that are not paid under the PFS. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are not paid under the PFS.

We note that these impacts do not include the effect of the April 2015 conversion factor changes under current law. The annual update to the PFS conversion factor is calculated based on a statutory formula that measures actual versus allowed or “target” expenditures, and applies a sustainable growth rate (SGR) calculation intended to control growth in aggregate Medicare expenditures for physicians’ services. This update methodology is typically referred to as the “SGR” methodology, although the SGR is only one component of the formula. Medicare PFS payments for services are not withheld if the percentage increase in actual expenditures exceeds the SGR. Rather, the PFS update, as specified in section 1848(d)(4) of the Act, is adjusted to eventually bring actual expenditures back in line with targets. If actual expenditures exceed allowed expenditures, the update is reduced. If actual expenditures are less than allowed expenditures, the update is increased. By law, we are required to apply these updates in accordance with sections 1848(d) and (f) of the Act, and any negative updates can only be averted by an Act of the Congress.

Although the Congress has provided temporary relief from negative updates for every year since 2003, a long-term solution is critical. We are committed to working with the Congress to reform Medicare physician payments to provide predictable payments that incentivize quality and efficiency in a fiscally responsible way. We provide our most recent estimate of the SGR and physician update for CY 2015 on our Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SustainableGRatesConFact/index.html?redirect=/SustainableGRatesConFact/>.

Table 93 shows the payment impact on PFS services. To the extent that there are year-to-year changes in the volume and mix of services provided by physicians, the actual impact on total Medicare revenues will be different from those shown in Table 93 (CY 2015 PFS Final Rule with Comment Period Estimated Impact on Total Allowed Charges by Specialty).

The following is an explanation of the information represented in Table 93:

- *Column A (Specialty)*: The Medicare specialty code as reflected in our physician/supplier enrollment files.
- *Column B (Allowed Charges)*: The aggregate estimated PFS allowed charges for the specialty based on CY 2013 utilization and CY 2014 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- *Column C (Impact of Work RVU Changes)*: This column shows the estimated CY 2015 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to new, revised, and misvalued codes.

- *Column D (Impact of PE RVU Changes)*: This column shows the estimated CY 2015 impact on total allowed charges of the changes in the PE RVUs, including the impact of changes due to new, revised, and misvalued codes, the film-to-digital migration of imaging inputs, and other miscellaneous and minor provisions.

- *Column E (Impact of Malpractice (MP) Changes)*: This column shows the estimated CY 2015 impact on total allowed charges of the changes in the MP RVUs, which are primarily driven by the required five year review and update of MP RVUs.

- *Column F (Cumulative Impact)*: This column shows the estimated CY 2015 combined impact on total allowed charges of all the changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.

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**TABLE 93: CY 2015 PFS Final Rule with Comment Period Estimated Impact Table:
Impacts of Work, Practice Expense, and Malpractice RVUs**

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
TOTAL	\$88,045	0%	0%	0%	0%
ALLERGY/IMMUNOLOGY	\$216	0%	0%	0%	0%
ANESTHESIOLOGY	\$1,993	0%	0%	0%	0%
AUDIOLOGIST	\$60	0%	0%	0%	0%
CARDIAC SURGERY	\$355	0%	0%	-1%	-1%
CARDIOLOGY	\$6,470	0%	0%	0%	0%
CHIROPRACTOR	\$812	0%	0%	-1%	-1%
CLINICAL PSYCHOLOGIST	\$704	0%	-1%	0%	-1%
CLINICAL SOCIAL WORKER	\$522	0%	-1%	0%	-1%
COLON AND RECTAL SURGERY	\$159	0%	0%	0%	0%
CRITICAL CARE	\$287	0%	0%	0%	0%
DERMATOLOGY	\$3,177	0%	-1%	0%	-2%
DIAGNOSTIC TESTING FACILITY	\$715	0%	-2%	0%	-2%
EMERGENCY MEDICINE	\$3,046	0%	0%	1%	1%
ENDOCRINOLOGY	\$457	0%	0%	0%	0%
FAMILY PRACTICE	\$6,107	1%	1%	0%	1%
GASTROENTEROLOGY	\$1,884	0%	0%	0%	0%
GENERAL PRACTICE	\$506	0%	0%	0%	0%
GENERAL SURGERY	\$2,245	0%	0%	0%	0%
GERIATRICS	\$227	1%	1%	0%	1%
HAND SURGERY	\$160	0%	0%	0%	0%
HEMATOLOGY/ONCOLOGY	\$1,811	0%	1%	0%	1%
INDEPENDENT LABORATORY	\$714	-1%	0%	0%	-1%
INFECTIOUS DISEASE	\$652	0%	0%	0%	1%
INTERNAL MEDICINE	\$11,123	1%	1%	0%	1%
INTERVENTIONAL PAIN MGMT	\$678	0%	1%	0%	0%
INTERVENTIONAL RADIOLOGY	\$273	0%	1%	0%	0%
MULTISPECIALTY CLINIC/OTHER PHY	\$84	0%	0%	0%	0%
NEPHROLOGY	\$2,181	0%	0%	0%	0%
NEUROLOGY	\$1,513	0%	0%	0%	0%
NEUROSURGERY	\$740	0%	0%	1%	1%
NUCLEAR MEDICINE	\$49	0%	0%	0%	0%
NURSE ANES / ANES ASST	\$1,186	0%	0%	0%	0%
NURSE PRACTITIONER	\$2,224	0%	0%	0%	1%
OBSTETRICS/GYNECOLOGY	\$696	0%	0%	0%	-1%
OPHTHALMOLOGY	\$5,685	0%	0%	-2%	-2%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
OPTOMETRY	\$1,163	0%	0%	-1%	-1%
ORAL/MAXILLOFACIAL SURGERY	\$45	0%	0%	0%	0%
ORTHOPEDIC SURGERY	\$3,672	0%	0%	0%	-1%
OTHER	\$28	0%	0%	-1%	-1%
OTOLARNGOLOGY	\$1,174	0%	0%	0%	0%
PATHOLOGY	\$1,077	-1%	1%	0%	0%
PEDIATRICS	\$59	0%	0%	0%	0%
PHYSICAL MEDICINE	\$1,008	0%	0%	0%	0%
PHYSICAL/OCCUPATIONAL THERAPY	\$2,836	0%	0%	1%	1%
PHYSICIAN ASSISTANT	\$1,565	0%	0%	0%	0%
PLASTIC SURGERY	\$374	0%	0%	-1%	0%
PODIATRY	\$2,001	0%	0%	0%	0%
PORTABLE X-RAY SUPPLIER	\$112	0%	-2%	0%	-2%
PSYCHIATRY	\$1,352	0%	0%	0%	0%
PULMONARY DISEASE	\$1,795	0%	0%	0%	0%
RADIATION ONCOLOGY	\$1,794	0%	0%	0%	0%
RADIATION THERAPY CENTERS	\$57	0%	0%	0%	1%
RADIOLOGY	\$4,523	0%	-1%	0%	-1%
RHEUMATOLOGY	\$541	0%	0%	0%	-1%
THORACIC SURGERY	\$343	0%	0%	-1%	-1%
UROLOGY	\$1,838	0%	0%	0%	0%
VASCULAR SURGERY	\$978	0%	0%	0%	0%

Note: Table 93 shows only the payment impact on PFS services. These impacts use a constant conversion factor and thus do not include the effects of the April 2015 conversion factor change required under current law.

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2. CY 2015 PFS Impact Discussion

a. Work RVU Impacts

The changes in work RVU impacts are almost entirely attributable to the payment for CCM services beginning in CY 2015. We finalized this separately billable CCM service in the CY 2014 final rule with comment period, effective beginning in CY 2015 (78 FR 74414 through 74427). We are finalizing a payment rate for CCM services for CY 2015 (see section II.G. of this final rule with comment period.) Payment for this service is expected to result in modest payment increases for family practice, internal medicine, and geriatrics.

b. PE RVU Impacts

Payment for CCM services also has a positive impact on the PE RVUs attributable to family practice, internal medicine, and geriatrics. The most widespread specialty impacts in PE RVUs are generally related implementing the RUC recommendation regarding the film-to-digital migration of imaging inputs, which primarily affects portable x-ray suppliers, diagnostic testing facilities, and interventional radiology. Other impacts result from adjustments of PE RVUs for services as discussed in section II.A. of this final rule with comment period.

c. MP RVU Impacts

The changes in MP RVUs are primarily attributable to the changes made as part of the statutorily required

review of MP RVUs every five years as described in section II.C of this final rule with comment period. Of particular note are the impacts on the specialties of ophthalmology (– 2 percent) and optometry (– 1 percent). In the course of preparation of the proposed MP RVUs, we discovered that we had made an error in calculating the MP RVUs for ophthalmology codes in the last five year review CY that resulted in higher MP RVUs for ophthalmology and optometry for CY 2010 than would have resulted had the MP RVUs been calculated correctly. The MP RVUs have been at a level higher than they would have been had they been calculated correctly since CY 2010.

d. Combined Impact

Column F of Table 93 displays the estimated CY 2015 combined impact on total allowed charges by specialty of all the RVU changes. These impacts are estimated prior to the application of the negative CF update effective April 1, 2015, applicable under the current statute.

Table 94 (Impact of Final rule with comment period on CY 2015 Payment for Selected Procedures) shows the estimated impact on total payments for selected high volume procedures of all of the changes discussed previously. We have included payment rates for the period of January 1, 2015 through March 31, 2015, as well as those for April 1, 2015 through December 31, 2015. We

selected these procedures for the sake of illustration from among the most commonly furnished by a broad spectrum of specialties. The change in both facility rates and the nonfacility rates are shown. For an explanation of facility and nonfacility PE, we refer readers to Addendum A of this final rule with comment period.

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TABLE 94: Impact of Final Rule with Comment Period on CY 2014 Payment for Selected Procedures

CPT/ HCPCS ¹	MOD	Short Descriptor	Facility					Non-Facility				
			CY 2014 ²	CY 2015 Jan 1 – March 31 ³	% Change	CY 2015 April 1 – December 31 ⁴	% Change	CY 2014 ²	CY 2015 Jan 1 – March 31 ³	% Change	CY 2015 April 1 – December 31 ⁴	% Change
11721		Debride nail 6 or more	\$25.43	\$25.42	0%	\$20.04	-21%	\$45.14	\$45.47	1%	\$35.84	-21%
17000		Destruct premalg lesion	\$53.38	\$53.70	1%	\$42.34	-21%	\$75.23	\$66.95	-11%	\$52.78	-30%
27130		Total hip arthroplasty	\$1,395.30	\$1,399.11	0%	\$1,102.99	-21%	NA	NA	NA	NA	NA
27244		Treat thigh fracture	\$1,262.04	\$1,270.23	1%	\$1,001.38	-21%	NA	NA	NA	NA	NA
27447		Total knee arthroplasty	\$1,394.58	\$1,398.76	0%	\$1,102.08	-21%	NA	NA	NA	NA	NA
33533		Cabg arterial single	\$1,956.28	\$1,936.13	-1%	\$1,526.35	-22%	NA	NA	NA	NA	NA
35301		Rechanneling of artery	\$1,200.42	\$1,192.90	-1%	\$940.42	-22%	NA	NA	NA	NA	NA
43239		Egd biopsy single/multiple	\$152.25	\$152.16	0%	\$119.95	-21%	\$405.51	\$409.92	1%	\$323.16	-20%
66821		After cataract laser	\$324.55	\$315.05	-3%	\$248.37	-23%	\$342.47	\$333.67	-3%	\$263.05	-23%
66984		Cataract surg w/iol 1 stage	\$673.11	\$647.65	-4%	\$510.57	-24%	NA	NA	NA	NA	NA
67210		Treatment of retinal lesion	\$523.37	\$506.95	-3%	\$399.58	-24%	\$540.92	\$524.49	-3%	\$413.48	-24%
71010		Chest x-ray 1 view frontal	NA	NA	NA	NA	NA	\$24.00	\$22.55	-6%	\$17.78	-26%
71010	26	Chest x-ray 1 view frontal	\$9.31	\$9.31	0%	\$7.34	-21%	\$9.31	\$9.31	0%	\$7.34	-21%
77056		Mammogram both breasts	NA	NA	NA	NA	NA	\$116.07	\$116.00	0%	\$91.45	-21%
77056	26	Mammogram both breasts	\$44.42	\$44.39	0%	\$35.00	-21%	\$44.42	\$44.39	0%	\$35.00	-21%
77057		Mammogram screening	NA	NA	NA	NA	NA	\$82.75	\$82.70	0%	\$65.20	-21%
77057	26	Mammogram screening	\$35.82	\$35.80	0%	\$28.22	-21%	\$35.82	\$35.80	0%	\$28.22	-21%
77427		Radiation tx management	\$186.28	\$186.17	0%	\$146.76	-21%	\$186.28	\$186.17	0%	\$146.76	-21%
88305	26	Tissue exam by	\$38.33	\$39.02	2%	\$30.76	-20%	\$38.33	\$39.02	2%	\$30.76	-20%
90935		Hemodialysis one	\$73.44	\$73.03	-1%	\$57.58	-22%	NA	NA	NA	NA	NA
92012		Eye exam establish patient	\$54.81	\$52.99	-3%	\$41.77	-24%	\$87.05	\$85.57	-2%	\$67.46	-23%
92014		Eye exam&tx estab pt	\$82.75	\$80.55	-3%	\$63.50	-23%	\$126.10	\$124.23	-1%	\$97.94	-22%
93000		Electrocardiogram	NA	NA	NA	NA	NA	\$16.84	\$17.18	2%	\$13.55	-20%
93010		Electrocardiogram report	\$8.60	\$8.59	0%	\$6.77	-21%	\$8.60	\$8.59	0%	\$6.77	-21%

CPT/ HCPCS ¹	MOD	Short Descriptor	Facility					Non-Facility				
			CY 2014 ²	CY 2015 Jan 1 – March 31 ³	% Change	CY 2015 April 1 – December 31 ⁴	% Change	CY 2014 ²	CY 2015 Jan 1 – March 31 ³	% Change	CY 2015 April 1 – December 31 ⁴	% Change
93015		Cardiovascular stress test	NA	NA	NA	NA	NA	\$75.94	\$76.97	1%	\$60.68	-20%
93307	26	Tte w/o doppler complete	\$45.85	\$45.83	0%	\$36.13	-21%	\$45.85	\$45.83	0%	\$36.13	-21%
93458	26	L hrt artery/ventricle	\$325.63	\$321.14	-1%	\$253.17	-22%	\$325.63	\$321.14	-1%	\$253.17	-22%
98941		Chiropract manj 3-4	\$35.46	\$35.09	-1%	\$27.66	-22%	\$41.55	\$41.17	-1%	\$32.46	-22%
99203		Office/outpatient visit new	\$77.02	\$77.69	1%	\$61.25	-20%	\$108.18	\$109.19	1%	\$86.08	-20%
99213		Office/outpatient visit est	\$51.58	\$51.20	-1%	\$40.36	-22%	\$73.08	\$73.03	0%	\$57.58	-21%
99214		Office/outpatient visit est	\$79.17	\$78.76	-1%	\$62.09	-22%	\$107.83	\$107.76	0%	\$84.95	-21%
99222		Initial hospital care	\$138.63	\$138.55	0%	\$109.23	-21%	NA	NA	NA	NA	NA
99223		Initial hospital care	\$204.19	\$204.07	0%	\$160.80	-21%	NA	NA	NA	NA	NA
99231		Subsequent hospital care	\$39.41	\$39.38	0%	\$31.05	-21%	NA	NA	NA	NA	NA
99232		Subsequent hospital care	\$72.36	\$73.03	1%	\$57.58	-20%	NA	NA	NA	NA	NA
99233		Subsequent hospital care	\$104.24	\$105.61	1%	\$83.26	-20%	NA	NA	NA	NA	NA
99236		Observ/hosp same date	\$219.24	\$219.82	0%	\$173.29	-21%	NA	NA	NA	NA	NA
99239		Hospital discharge day	\$107.47	\$108.12	1%	\$85.24	-21%	NA	NA	NA	NA	NA
99283		Emergency dept visit	\$61.97	\$62.29	1%	\$49.11	-21%	NA	NA	NA	NA	NA
99284		Emergency dept visit	\$118.22	\$119.22	1%	\$93.99	-20%	NA	NA	NA	NA	NA
99291		Critical care first hour	\$224.61	\$225.91	1%	\$178.09	-21%	\$274.76	\$277.10	1%	\$218.45	-20%
99292		Critical care addl 30 min	\$112.48	\$113.13	1%	\$89.19	-21%	\$123.23	\$124.23	1%	\$97.94	-21%
99348		Home visit est patient	NA	NA	NA	NA	NA	\$84.54	\$84.13	0%	\$66.33	-22%
99350		Home visit est patient	NA	NA	NA	NA	NA	\$178.40	\$177.93	0%	\$140.27	-21%
G0008		Immunization admin	NA	NA	NA	NA	NA	\$25.08	\$25.42	1%	\$20.04	-20%

¹ CPT codes and descriptions are copyright 2014 American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.

² The CY 2014 conversion factor is 35.8228.

³ Payments based on the CY 2015 conversion factor of 35.8013 effective January 1 – March 31.

⁴ Payments based on the CY 2015 conversion factor of 28.2239 effective April 1.

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D. Effect of Changes to Medicare Telehealth Services Under the PFS
As discussed in section II.F. of this final rule with comment period, we are finalizing the addition of several new codes to the list of Medicare telehealth services. Although we expect these changes to increase access to care in

rural areas, based on recent utilization of similar services already on the telehealth list, we estimate no significant impact on PFS expenditures from these additions.

E. Geographic Practice Cost Indices (GPCIs)

As discussed in section II.D of this final rule with comment period, we are required to review and revise the GPCIs at least every 3 years and phase in the adjustment over 2 years (if there has not been an adjustment in the past year). For CY 2015, we are not making any revisions related to the data or the methodologies used to calculate the GPCIs except in regard to the Virgin Islands locality discussed in section II.D. However, since the 1.0 work GPCI floor provided in section 1848(e)(1)(E) of the Act is set to expire on March 31, 2015, we have included two set of GPCIs and GAFs for CY 2015—one set for January 1, 2015 through March 31, 2015 and another set for April 1, 2015 through December 31, 2015. The April 1, 2015 through December 31, 2015 GPCIs and GAFs reflect the statutory expiration of the 1.0 work GPCI floor.

F. Other Provisions of the Final Rule With Comment Period Regulation

1. Ambulance Fee Schedule

The statutory ambulance extender provisions are self-implementing. As a result, there are no policy proposals associated with these provisions or associated impact in this rule. We are finalizing our proposal to correct the dates in the Code of Federal Regulations (CFR) at § 414.610(c)(1)(ii) and § 414.610(c)(5)(ii) to conform the regulations to these self-implementing statutory provisions.

The geographic designations for approximately 92.02 percent of ZIP codes would be unchanged if we adopt OMB's revised statistical area delineations and the updated RUCA codes. There are more ZIP codes that would change from rural to urban (3,038 or 7.08 percent) than from urban to rural (387 or 0.90 percent). The differences in the data provided in the proposed rule compared to the final rule are due to inclusion of the updated RUCA codes. In general, it is expected that ambulance providers and suppliers in 387 ZIP codes within 41 states may experience payment increases under the revised OMB delineations and the updated RUCA codes, as these areas have been redesignated from urban to rural. Ambulance providers and suppliers in 3,038 ZIP codes within 46 states and Puerto Rico may experience payment decreases under the revised OMB

delineations and the updated RUCA codes, as these areas have been redesignated from rural to urban. None of the current super rural areas will lose their status upon implementation of the revised OMB delineations and the updated RUCA codes. We estimate that the adoption of the revised OMB delineations and the updated RUCA codes would have a small fiscal impact on the Medicare program.

2. Clinical Laboratory Fee Schedule

There is no impact because we are merely deleting language from the Code of Federal Regulations.

3. Removal of Employment Requirements for Services Furnished "Incident to" RHC and FQHC Visits

The removal of employment requirements for services furnished "incident to" RHC and FQHC visits will provide RHCs and FQHCs with greater flexibility in meeting their staffing needs, which may result in increasing access to care in underserved areas. There is no cost to the federal government, and we cannot estimate a cost savings for RHCs or FQHCs.

4. Access to Identifiable Data for the Center for Medicare and Medicaid Models

Given that, in general, participants in Innovation Center models receive funding support to participate in model tests, we do not anticipate an impact. In those cases where there is a cost associated with the data reporting, such costs will vary by project, and thus cannot be laid out with specificity here. We do, however, expect the costs to be covered by payments associated with the model test.

5. Local Coverage Determination Process for Clinical Diagnostic Laboratory Tests

The Local Coverage Determination Process for Clinical Diagnostic Laboratory Tests will not be finalized. Therefore, there is no impact to CY 2015 physician payments under the PFS.

6. Private Contracting/Opt Out

We corrected cross-references and outdated terminology in the regulations that we inadvertently neglected to revise, and changed the appeals process used for certain appeals relating to opt-out private contracting. We anticipate no or minimal impact as a result of these corrections.

7. Payment Policy for Locum Tenens Physicians

We did not issue any new or revised requirements. There is no impact.

8. Reports of Payments or Other Transfers of Value to Covered Recipients

The changes to the Transparency Reports and Reporting of Physician Ownership or Investment Interests in section III.I of this final rule with comment period would not impact CY 2015 physician payments under the PFS.

9. Physician Compare

There will be no impact for the Physician Compare Web site because we are not collecting any new information specifically for the Physician Compare Web site. The information derived for Physician Compare comes from other programs that already collect data, including but not limited to the Physician Quality Reporting System (PQRS) and the Medicare Shared Savings Program.

10. Physician Quality Reporting System

According to the 2012 Reporting Experience, "more than 1.2 million eligible professionals were eligible to participate in the 2012 PQRS, Medicare Shared Savings Program, and Pioneer ACO Model."⁴⁰ In this burden estimate, we assume that 1.2 million eligible professionals, the same number of eligible professionals eligible to participate in the PQRS in 2012, will be eligible to participate in the PQRS. Since all eligible professionals are subject to the 2017 PQRS payment adjustment, we estimate that all 1.2 million eligible professionals will participate, (which includes, for the purposes of this discussion, being eligible for the 2017 PQRS payment adjustment) in the PQRS in 2015 for purposes of meeting the criteria for satisfactory reporting (or, in lieu of satisfactory reporting, satisfactory participation in a QCDR) for the 2017 PQRS payment adjustment.

Historically, the PQRS has never experienced 100 percent participation in reporting for the PQRS. Therefore, we believe that although 1.2 million eligible professionals will be subject to the 2017 PQRS payment adjustment, not all eligible participants will actually report quality measures data for purposes of the 2017 PQRS payment adjustment. In this burden estimate, we will only provide burden estimates for the eligible professionals and group practices who attempt to submit quality measures data for purposes of the 2017 PQRS payment

⁴⁰ Centers for Medicare and Medicaid Services, *2012 Reporting Experience Including Trends (2007–2013): Physician Quality Reporting System and Electronic Prescribing (eRx) Incentive Program*, March 14, 2014, at xiii.

adjustment. In 2012, 435,871 eligible professionals (36 percent) eligible professionals (including those who belonged to group practices that reported under the GPRO and eligible professionals within an ACO that participated in the PQRS via the Shared Savings Program or Pioneer ACO Model) participated in the PQRS, Medicare Shared Savings Program, or Pioneer ACO Model.⁴¹ We expect to see a significant increase in participation in reporting for the PQRS in 2015 than 2012 as eligible professionals were not subject to a PQRS payment adjustment in 2012. Last year (78 FR 74793), we estimated that we would see a 50 percent participation rate in 2015. We still believe that a 14 percent increase in participation from 2012 is reasonable in 2015. Therefore, we estimate that 50 percent of eligible professionals (or approximately 600,000 eligible professionals) will report quality measures data for purposes of the 2017 PQRS payment adjustment.

For participation in the PQRS using the claims-based reporting mechanism, according to the 2011 PQRS and eRx Experience Report, in 2011, 229,282 of the 320,422 eligible professionals (or 72 percent) of eligible professionals used the claims-based reporting mechanism. According to the 2012 Reporting Experience, 248,206 eligible professionals participated in the PQRS using the claims-based reporting mechanism in 2012.⁴² Preliminary estimates show that 252,567 eligible professionals participated in the PQRS using the claims-based reporting mechanism in 2013.⁴³ According to the historical data cited above, although the claims-based reporting mechanism is still the most widely-used reporting mechanism, we are seeing a decline in the percentage of participants using the claims-based reporting mechanism in the PQRS. Although these eligible professionals continue to participate in the PQRS, these eligible professionals have started to shift towards the use of other reporting mechanisms—mainly the GPRO web interface (whether used by a PQRS GPRO or an ACO participating in the PQRS via the Medicare Shared Savings Program or Pioneer ACO model), registry, or the EHR-based reporting mechanisms. For purposes of this burden estimate, based on PQRS participation using the claims-based reporting mechanism in 2012 and 2013, we will assume that approximately 250,000 eligible professionals will participate in the

PQRS using the claims-based reporting mechanism.

For participation in the PQRS using a qualified registry or QCDR, in 2011, approximately 50,215 (or 16 percent) of the 320,422 eligible professionals participating in PQRS used the qualified registry-based reporting mechanism. According to the 2012 Reporting Experience, 36,473 eligible professionals reported individual measures via the registry-based reporting mechanism, and 10,478 eligible professionals reporting measures groups via the registry-based reporting mechanism in 2012.⁴⁴ Therefore, approximately 47,000 eligible professionals participated in the PQRS using the registry-based reporting mechanism in 2012. Please note that we currently have no data on participation in the PQRS via a QCDR as 2014 is the first year in which an eligible professional may participate in the PQRS via a QCDR. We believe that the rest of the eligible professionals not participating in other PQRS reporting mechanisms will use either the registry or QCDR reporting mechanisms for the following reasons: (1) The PQRS measures set is moving away from use of claims-based measures and moving towards the use of registry-based measures; or (2) we believe the number of QCDR vendors will increase as the QCDR reporting mechanism evolves. Therefore, based on these assumptions, we expect to see a significant jump from 47,000 eligible professionals (the remaining number of eligible professionals not participating via the claims, EHR, or GPRO web interface reporting mechanisms) to approximately 165,000 eligible professionals using either the registry-based reporting mechanism or QCDR in 2015. We believe the majority of these eligible professionals will participate in the PQRS using a QCDR, as we presume QCDRs will be larger entities with more members.

For participation in the PQRS using the EHR-based reporting mechanism, according to the 2011 PQRS and eRx Experience Report, in 2011, 560 (or less than 1 percent) of the 320,422 eligible professionals participating in PQRS used the EHR-based reporting mechanism. 2012 saw a sharp increase in reporting via the EHR-based reporting mechanism. Specifically, according to the 2012 Reporting Experience, in 2012, 19,817 eligible professionals submitted quality data for the PQRS through a qualified EHR.⁴⁵ We believe the number of eligible professionals and group

practices using the EHR-based reporting mechanism will steadily increase as eligible professionals become more familiar with EHR products and more eligible professionals participate in programs encouraging use of an EHR, such as the EHR Incentive Program. In particular, we believe eligible professionals will transition from using the claims-based to the EHR-based reporting mechanisms. To account for this anticipated increase, we continue to estimate that approximately 50,000 eligible professionals, whether participating as an individual or part of a group practice under the GPRO, would use the EHR-based reporting mechanism in CY 2015.

For participation in the PQRS using the GPRO web interface, as we noted in last year's estimate, according to the 2011 Experience Report, approximately 200 group practices participated in the GPRO in 2011. According to the 2012 Reporting Experience, 66 practices participated in the PQRS GPRO.⁴⁶ In addition, 144 ACOs participated in the PQRS GPRO through either the Medicare Shared Savings Program (112 ACOs) or Pioneer ACO Model (32 practices).⁴⁷ These group practices encompass 134,510 eligible professionals (or approximately 140,000 eligible professionals).⁴⁸ Since it seems that roughly 200 group practices participated in the GPRO in 2011 and 2012, based on these numbers, we will assume that 200 group practices (accounting for approximately 135,000 eligible professionals) will participate in the PQRS using the GPRO web interface in 2015.

Please note that, while we are finalizing the reporting of CAHPS survey measures using a CMS-certified survey vendor, we are not including this reporting mechanism in this impact statement as we believe that eligible professionals wishing to report CAHPS survey measures will do so for purposes other than the PQRS.

(a) Assumptions for Burden Estimates

For the PQRS, the burden associated with the requirements of this voluntary reporting initiative is the time and effort associated with individual eligible professionals identifying applicable quality measures for which they can report the necessary information, selecting a reporting option, and reporting the information on their selected measures or measures group to CMS using their selected reporting option.

⁴¹ Id. at XV.

⁴² Id. at xvi. See Figure 4.

⁴³ Id.

⁴⁴ Id. at xvi. See Figure 4.

⁴⁵ Id. at xvi.

⁴⁶ Id. at xv.

⁴⁷ Id. at xvi.

⁴⁸ Id. at 18.

We believe the labor associated with eligible professionals and group practices reporting quality measures data in the PQRS is primarily handled by an eligible professional's or group practice's billing clerk or computer analyst trained to report quality measures data. Therefore, we will consider the hourly wage of a billing clerk and computer analyst in our estimates. For purposes of this burden estimate, we will assume that a billing clerk will handle the administrative duties associated with participating in the PQRS. According to information published by the Bureau of Labor Statistics, available at <http://www.bls.gov/oes/2013/may/oes433021.htm>, the mean hourly wage for a billing clerk is approximately \$16.80/hour. Therefore, for purposes of handling administrative duties, we estimate an average labor cost of \$16.00/hour. In addition, for purposes of this burden estimate, we will assume that a computer analyst will engage in the duties associated with the reporting of quality measures. According to information published by the Bureau of Labor Statistics, available at <http://www.bls.gov/oes/2013/may/oes151121.htm>, the mean hourly wage for a computer analyst is approximately \$41.00/hour. Therefore, for purposes of reporting on quality measures, we estimate an average labor cost of \$41.00/hour. Please note that, in assessing the burden estimates below, to account for benefits and overhead associated with labor in addition to the hourly wage costs described above, we are doubling the wage rates in our estimates.

For individual eligible professionals, the burden associated with the requirements of this reporting initiative is the time and effort associated with eligible professionals identifying applicable quality measures for which they can report the necessary information, collecting the necessary information, and reporting the information needed to report the eligible professional's measures. We believe it is difficult to accurately quantify the burden because eligible professionals may have different processes for integrating the PQRS into their practice's work flows. Moreover, the time needed for an eligible professional to review the quality measures and other information, select measures applicable to his or her patients and the services he or she furnishes to them, and incorporate the use of quality data codes into the office work flows is expected to vary along with the number of measures that are potentially applicable to a given professional's

practice. Since eligible professionals are generally required to report on at least 9 measures covering at least 3 National Quality Strategy domains criteria for satisfactory reporting (or, in lieu of satisfactory reporting, satisfactory participation in a QCDR) for the 2017 PQRS payment adjustment, we will assume that each eligible professional reports on an average of 9 measures for this burden analysis.

For eligible professionals who are participating in PQRS for the first time, we will assign 5 total hours as the amount of time needed for an eligible professional's billing clerk to review the PQRS Measures List, review the various reporting options, select the most appropriate reporting option, identify the applicable measures or measures groups for which they can report the necessary information, review the measure specifications for the selected measures or measures groups, and incorporate reporting of the selected measures or measures groups into the office work flows. The measures list contains the measure title and brief summary information for the eligible professional to review. Assuming the eligible professional has received no training from his/her specialty society, we estimate it will take an eligible professional's billing clerk up to 2 hours to review this list, review the reporting options, and select a reporting option and measures on which to report. If an eligible professional has received training, then we believe this would take less time. We believe 3 hours is plenty of time for an eligible professional to review the measure specifications of 9 measures or 1 measures group they select to report for purposes of participating in PQRS and to develop a mechanism for incorporating reporting of the selected measures or measures group into the office work flows. Therefore, we believe that the start-up cost for an eligible professional to report PQRS quality measures data is 5 hours \times \$32/hour = \$160.

We believe the burden associated with actually reporting the quality measures will vary depending on the reporting mechanism selected by the eligible professional. As such, we break down the burden estimates by eligible professionals and group practices participating in the GPRO according to the reporting mechanism used.

(b) Burden Estimate for PQRS Reporting by Individual Eligible Professionals: Claims-Based Reporting Mechanism

For the claims-based reporting option, eligible professionals must gather the required information, select the

appropriate quality data codes (QDCs), and include the appropriate QDCs on the claims they submit for payment. The PQRS will collect QDCs as additional (optional) line items on the existing HIPAA transaction 837-P and/or CMS Form 1500 (OCN: 0938-0999). We do not anticipate any new forms and or any modifications to the existing transaction or form. We also do not anticipate changes to the 837-P or CMS Form 1500 for CY 2015.

We estimate the cost for an eligible professional to review the list of quality measures or measures groups, identify the applicable measures or measures group for which they can report the necessary information, incorporate reporting of the selected measures into the office work flows, and select a PQRS reporting option to be approximately \$410 per eligible professional (\$82 per hour \times 5 hours).

Based on our experience with the Physician Voluntary Reporting Program (PVRP), we continue to estimate that the time needed to perform all the steps necessary to report each measure (that is, reporting the relevant quality data code(s) for 9 measures measure) would range from 15 seconds (0.25 minutes) to over 12 minutes for complicated cases and/or measures, with the median time being 1.75 minutes. To report 9 measures, we estimate that it would take approximately 2.25 minutes to 108 minutes to perform all the steps necessary to report 9 measures.

Per measure, at an average labor cost of \$82/hour per practice, the cost associated with this burden will range from \$0.34 in labor to about \$16.40 in labor time for more complicated cases and/or measures, with the cost for the median practice being \$2.40. To report 9 measures, using an average labor cost of \$82/hour, we estimated that the time cost of reporting for an eligible professional via claims would range from \$3.07 (2.25 minutes or 0.0375 hours \times \$82/hour) to \$147.60 (108 minutes or 1.8 hours \times \$82/hour) per reported case.

The total estimated annual burden for this requirement will also vary along with the volume of claims on which quality data is reported. In previous years, when we required reporting on 80 percent of eligible cases for claims-based reporting, we found that on average, the median number of reporting instances for each of the PQRS measures was 9. Since we reduced the required reporting rate by over one-third to 50 percent, then for purposes of this burden analysis we will assume that an eligible professional or eligible professional in a group practice will need to report each selected measure for

6 reporting instances. The actual number of cases on which an eligible professional or group practice is required to report quality measures data will vary, however, with the eligible professional's or group practice's patient population and the types of measures on which the eligible professional or group practice chooses to report (each measure's specifications includes a required reporting frequency).

Based on the assumptions discussed previously, we estimate the total annual reporting burden per individual eligible professional associated with claims-based reporting will range from 13.5 minutes (0.25 minutes per measure \times 9 measures \times 6 cases per measure) to 648 minutes (12 minutes per measure \times 9 measures \times 6 cases per measure), with the burden to the median practice being 94.5 minutes (1.75 minutes per measure \times 9 measures \times 6 cases). We estimate the total annual reporting cost per eligible professional or eligible professional in a group practice associated with claims-based reporting will range from \$18.36 (\$0.34 per measure \times 9 measures \times 6 cases per measure) to \$885.60 (\$16.40 per measure \times 9 measures \times 6 cases per measure), with the cost to the median practice being \$129.60 per eligible professional (\$2.40 per measure \times 9 measures \times 6 cases per measure).

(c) Burden Estimate for PQRS Reporting by Individual Eligible Professionals and Group Practices: Qualified Registry-based and QCDR-based Reporting Mechanisms

For qualified registry-based and QCDR-based reporting, there will be no additional time burden for eligible professionals or group practices to report data to a qualified registry as eligible professionals and group practices opting for qualified registry-based reporting or use of a QCDR will more than likely already be reporting data to the qualified registry for other purposes and the qualified registry will merely be re-packaging the data for use in the PQRS. Little, if any, additional data will need to be reported to the qualified registry or QCDR solely for purposes of participation in the PQRS. However, eligible professionals and group practices will need to authorize or instruct the qualified registry or QCDR to submit quality measures results and numerator and denominator data on quality measures to CMS on their behalf. We estimate that the time and effort associated with this will be approximately 5 minutes per eligible professional or eligible professional within a group practice.

Based on the assumptions discussed above and in Part B of this supporting

statement, Table 95 provides an estimate of the total annual burden hours and total annual cost burden associated with eligible professionals using the qualified registry-based or QCDR-based reporting mechanism. Please note that, unlike the claims-based reporting mechanism that would require an eligible professional to report data to us on quality measures on multiple occasions, an eligible professional would not be required to submit this data to us, as the qualified registry or QCDR would perform this function on the eligible professional's behalf.

(d) Burden Estimate for PQRS Reporting by Individual Eligible Professionals and Group Practices: EHR-Based Reporting Mechanism

For EHR-based reporting, which includes EHR reporting via a direct EHR product and an EHR data submission vendor's product, the eligible professional or group practice must review the quality measures on which we will be accepting PQRS data extracted from EHRs, select the appropriate quality measures, extract the necessary clinical data from his or her EHR, and submit the necessary data to the our designated clinical data warehouse.

For EHR-based reporting for the PQRS, the individual eligible professional or group practice may either submit the quality measures data directly to us from their EHR or utilize an EHR data submission vendor to submit the data to us on the eligible professional's or group practice's behalf. To submit data to us directly from their EHR, the eligible professional or eligible professional in a group practice must have access to our specified identity management system, such as IACS, which we believe takes less than 1 hour to obtain. Once an eligible professional or eligible professional in a group practice has an account for our specified identity management system, he or she will need to extract the necessary clinical data from his or her EHR, and submit the necessary data to the our designated clinical data warehouse. With respect to submitting the actual data file for the respective reporting period, we believe that this will take an eligible professional or group practice no more than 2 hours, depending on the number of patients on which the eligible professional or group practice is submitting. We believe that once the EHR is programmed by the vendor to allow data submission to us, the burden to the eligible professional or group practice associated with submission of data on quality measures should be minimal as all of the information

required to report the measure should already reside in the eligible professional's or group practice's EHR.

(e) Burden Estimate for PQRS Reporting by Group Practices Using the GPRO Web Interface

With respect to the process for group practices to be treated as satisfactorily submitting quality measures data under the PQRS, group practices interested in participating in the PQRS through the group practice reporting option (GPRO) must complete a self-nomination process similar to the self-nomination process required of qualified registries. However, since a group practice using the GPRO web interface would not need to determine which measures to report under PQRS, we believe that the self-nomination process is handled by a group practice's administrative staff. Therefore, we estimate that the self-nomination process for the group practices for the PQRS involves approximately 2 hours per group practice to review the PQRS GPRO and make the decision to participate as a group rather than individually and an additional 2 hours per group practice to draft the letter of intent for self-nomination, gather the requested TIN and NPI information, and provide this requested information. It is estimated that each self-nominated entity will also spend 2 hours undergoing the vetting process with CMS officials. We assume that the group practice staff involved in the group practice self-nomination process has an average practice labor cost of \$32 per hour. Therefore, assuming the total burden hours per group practice associated with the group practice self-nomination process is 6 hours, we estimate the total cost to a group practice associated with the group practice self-nomination process to be approximately \$192 (\$32 per hour \times 6 hours per group practice).

The burden associated with the group practice reporting requirements under the GPRO is the time and effort associated with the group practice submitting the quality measures data. For physician group practices, this would be the time associated with the physician group completing the web interface. We estimate that the time and effort associated with using the GPRO web interface will be comparable to the time and effort associated to using the PAT. As stated above, the information collection components of the PAT have been reviewed by OMB and was approved under OMB control number 0938-0941—Form 10136, with an expiration date of December 31, 2011 for use in the PGP, MCMP, and EHR demonstrations. As the GPRO was only

recently implemented in 2010, it is difficult to determine the time and effort associated with the group practice submitting the quality measures data. As such, we will use the same burden estimate for group practices participating in the GPRO as we use for group practices participating in the PGP, MCMP, and EHR demonstrations. Since these changes will not have any impact on the information collection

requirements associated with the PAT and we will be using the same data submission process used in the PGP demonstration, we estimate that the burden associated with a group practice completing data for PQRS under the web interface will be the same as for the group practice to complete the PAT for the PGP demonstration. In other words, we estimate that, on average, it will take each group practice 79 hours to submit

quality measures data via the GPRO web interface at a cost of \$82 per hour. Therefore, the total estimated annual cost per group practice is estimated to be approximately \$6,478.

Tables 95 and 96 provide our total estimated costs for reporting in the PQRS for the 2017 PQRS payment adjustment, the reporting periods of which occur in CY 2015.

TABLE 95—SUMMARY OF BURDEN ESTIMATES FOR ELIGIBLE PROFESSIONALS AND/OR GROUP PRACTICES USING THE CLAIMS, QUALIFIED REGISTRY, AND EHR-BASED REPORTING MECHANISMS FOR THE 2017 PQRS PAYMENT ADJUSTMENT

	Minimum burden estimate	Maximum burden estimate
Estimated Annual Burden Hours for Claims-based Reporting (for individual eligible professionals only)	1,306,025	3,948,920
Estimated Annual Burden Hours for Qualified registry-based or QCDR-based Reporting	1,333,695	1,333,695
Estimated Annual Burden Hours for EHR-based Reporting	450,000	450,000
Estimated Total Annual Burden Hours for Eligible Professionals or Eligible Professionals in a Group Practice	3,089,720	5,732,615
Estimated Cost for Claims-based Reporting (for individual eligible professionals only)	\$107,090,000	\$323,900,000
Estimated Cost for Qualified registry-based Reporting	\$109,362,000	\$109,362,000
Estimated Cost for EHR-based Reporting	\$32,800,000	\$32,800,000
Estimated Total Annual Cost for Eligible Professionals or Eligible Professionals in a Group Practice	\$249,252,000	\$466,062,000

TABLE 96—ESTIMATED COSTS OF GROUP PRACTICES USING THE GPRO WEB INTERFACE TO PARTICIPATE IN THE PQRS FOR THE 2017 PQRS PAYMENT ADJUSTMENT

	Maximum burden estimate
Estimated # of Participating Group Practices	200
Estimated # of Burden Hours Per Group Practice to Self-Nominate to Participate in PQRS and the Electronic Prescribing Incentive Program Under the Group Practice Reporting Option	6
Estimated # of Burden Hours Per Group Practice to Report Quality Measures	79
Estimated Total Annual Burden Hours Per Group Practice	85
Estimated Total Annual Burden Hours for Group Practices	17,000
Estimated Cost Per Group Practice to Self-Nominate to Participate in PQRS for the Group Practice Reporting Option	\$192
Estimated Cost Per Group Practice to Report Quality Measures	\$6,478
Estimated Total Annual Cost Per Group Practice	\$6,670
Annual Burden Cost for Group Practices	\$1,334,000

11. EHR Incentive Program

The changes to the EHR Incentive Program in section III.L of this final rule with comment period would not impact CY 2015 physician payments under the PFS.

12. Medicare Shared Saving Program

The requirements for participating in the Medicare Shared Saving Program and the impacts of these requirements were established in the final rule implementing the Medicare Shared Savings Program that appeared in the **Federal Register** on November 2, 2011 (76 FR 67802). The proposals for the Medicare Shared Savings Program set forth in the CY 2015 MPFS proposed rule revisited the current quality performance standard, proposed changes to the quality measures, proposed modifications to the timeframe between updates to the quality performance benchmarks, and

proposed to establish an additional incentive to reward ACO quality improvement. Since the policies being adopted in this final rule with comment period do not increase the quality reporting burden for ACOs participating in the Shared Savings Program and their ACO participants and ACO providers/suppliers, there is no impact for these policies.

13. Value-Based Payment Modifier and the Physician Feedback Program

Section 1848(p) of the Act requires that we establish a VM and apply it to specific physicians and groups of physicians the Secretary determines appropriate starting January 1, 2015 and to all physicians and groups of physicians by January 1, 2017. Section 1848(p)(4)(C) of the Act requires the VM to be budget neutral. Budget-neutrality means that, in aggregate, the increased payments to high performing physicians

and groups of physicians equal the reduced payments to low performing physicians and groups of physicians.

The changes to the VM in section III.N of this final rule with comment period will not impact CY 2015 physician payments under the PFS. We finalized the VM policies that would impact the CY 2015 physician payments under the PFS in the CY 2013 PFS final rule with comment period (77 FR 69306–69326).

In the CY 2013 PFS final rule with comment period, we finalized policies to phase-in the VM by applying it starting January 1, 2015 to payments under the Medicare PFS for physicians in groups of 100 or more eligible professionals. We identify a group of physicians as a single taxpayer identification number (TIN). We apply the VM to the items and services billed by physicians under the TIN, not to other eligible professionals that also may bill under the TIN. We established

CY 2013 as the performance period for the VM that will be applied to payments during CY 2015 (77 FR 69314). We also finalized that we will not apply the VM in CYs 2015 and 2016 to any group of physicians that is participating in the Medicare Shared Savings Program, the Pioneer ACO Model, or the Comprehensive Primary Care Initiative, or other similar Innovation Center or CMS initiatives (77 FR 69313).

We finalized policies to determine the amount of the VM for CY 2015 by categorizing groups of physicians with 100 or more eligible professionals into two categories. Category 1 includes groups of physicians that either (a) self-

nominate for the PQRS as a group and report at least one measure or (b) elect the PQRS Administrative Claims option as a group. Category 2 includes groups that do not fall within either of the two subcategories (a) or (b) of Category 1. Groups within Category 1 may elect to have their VM for CY 2015 calculated using the quality-tiering methodology, which could result in an upward, neutral, or downward adjustment amount. The VM for groups of physicians in Category 1 that do not elect quality tiering is 0.0 percent, meaning that these groups will not receive a payment adjustment under the VM for CY 2015. For the groups that are

in Category 2, the VM for the CY 2015 payment adjustment period is –1.0 percent.

Under the quality-tiering approach, each group's quality and cost composites are classified into high, average, and low categories depending upon whether the composites are at least one standard deviation above or below the mean. We compare the group's quality of care composite classification with the cost composite classification to determine the VM adjustment for the CY 2015 payment adjustment period according to the amounts in Table 97.

TABLE 97—2015 VALUE-BASED PAYMENT MODIFIER AMOUNTS UNDER QUALITY-TIERING

Cost/Quality	Low quality	Average quality	High quality
Low Cost	+0.0%	*+1.0x	*+2.0x
Average Cost	–0.5%	+0.0%	*+1.0x
High Cost	–1.0%	–0.5%	+0.0%

* Groups of physicians eligible for an additional +1.0x if (1) reporting Physician Quality Reporting System quality measures through the GPRO web-interface or CMS-qualified registry, and (2) average beneficiary risk score is in the top 25 percent of all beneficiary risk scores.

To ensure budget neutrality, we first aggregate the downward payment adjustments in Table 97 for those groups in Category 1 that have elected quality tiering with the –1.0 percent downward payment adjustments for groups of physicians subject to the VM that fall within Category 2. Using the aggregate downward payment adjustment amount, we then calculate the upward payment adjustment factor (x). These calculations will be done after the performance period has ended.

In the proposed rule, we presented estimates on the number of eligible professionals and physician groups, by group size, based on CY 2012 claims data that were used to produce the 2012 QRURs, which were available to groups of 25 or more eligible professionals on September 16, 2013. The findings from the CY 2012 QRURs are available on the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/2012-QRUR.html> in a document titled “Experience Report for the Performance Year 2012 Quality and Resource Use Reports”.

On September 30, 2014, we made QRURs available to all groups of physicians and physicians who are solo practitioners based on their performance in CY 2013. We also completed the

analysis of the impact of the VM in CY 2015 on physicians in groups with 100 or more eligible professionals based on their performance in CY 2013 and present a summary of the findings below. Please note that the impact of the policies for the CY 2017 VM finalized in this final rule with comment period will be discussed in the PFS rule for CY 2017.

Based on the methodology codified in § 414.1210(c), there are 1,010 groups of 100 or more eligible professionals (as identified by their Taxpayer Identification Numbers (TINs)) whose physicians' payments under the Medicare PFS will be subject to the VM in the CY 2015 payment adjustment period. Of these 1,010 groups subject to the CY 2015 VM, 706 groups met the criteria for inclusion in Category 1. As noted above, Category 1 for the CY 2015 VM includes groups of physicians that either (a) self-nominate for the PQRS as a group and report at least one measure or (b) elect the PQRS Administrative Claims option as a group.

Of the 706 groups in Category 1, 133 groups elected in 2013 to have their CY 2015 VM calculated using the quality-tiering methodology; therefore, these groups will receive an upward, neutral, or downward adjustment in CY 2015 based on their performance on the

quality and cost measures finalized for the CY 2015 VM in the CY 2013 PFS final rule with comment period (77 FR 69306–69326). We note that there were 21 groups for which we had insufficient data to calculate their quality or cost composite; therefore, these groups will receive a neutral adjustment to their payments in CY 2015. Of the 112 groups for which we were able to calculate both quality and cost composites, we found that 16 groups are in tiers that will result in an upward adjustment of +1.0x; 9 groups are in tiers that will result in a downward adjustment of between –0.5 and –1.0 percent; and 87 groups are in tiers that will result in a neutral adjustment to their payments in CY 2015. Of the groups that are eligible for an upward adjustment, none of the groups are eligible to receive an additional +1.0x adjustment to their Medicare payments for treating high-risk beneficiaries. Table 98 shows the distribution of the 112 groups that elected quality-tiering into the various quality and cost tiers. Please note that CMS will announce the upward payment adjustment factor (x) in the Fall of 2014 on the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/ValueBasedPaymentModifier.html>.

TABLE 98—DISTRIBUTION USING 2013 DATA OF QUALITY AND COST TIERS FOR GROUPS WITH 100 OR MORE ELIGIBLE PROFESSIONALS THAT ELECTED QUALITY-TIERING FOR WHICH A QUALITY AND COST COMPOSITE SCORE COULD BE CALCULATED (112 GROUPS)

Cost/Quality	Low quality	Average quality	High quality
Low Cost	+0.0% (0)	+1.0x (2)	+2.0x (0)
Average Cost	– 0.5% (5)	+0.0% (87)	+1.0x (14)
High Cost	– 1.0% (2)	– 0.5% (2)	+0.0% (0)

Of the 706 groups in Category 1, 573 groups elected to not have their CY 2015 VM calculated using the quality-tiering methodology; therefore, their VM will be 0.0 percent, meaning that these groups will not receive a payment adjustment under the VM in CY 2015.

Of the 1,010 groups subject to the CY 2015 VM, 304 groups met the criteria for inclusion in Category 2. As noted above, Category 2 includes groups that do not fall within either of the two subcategories (a) or (b) of Category 1. There were 289 groups that did not self-nominate for the PQRS as a group, and 15 groups that self-nominated for the PQRS as a group, but did not report at least one measure. Groups in Category 2 will be subject to a – 1.0 percent payment adjustment under the VM during the CY 2015 payment adjustment period.

Please note that in CY 2015, only the physicians in groups with 100 or more eligible professionals that are in Category 1 and elected quality-tiering will be subject to upward, downward, or no payment adjustment under the VM according to Table 98. Additionally, physicians in groups with 100 or more eligible professionals that fall in Category 2 will be subject to the – 1.0 percent VM in CY 2015.

We note that in the 2013 QRUR Experience Report, which will be released in the next few months, we will provide a detailed analysis of the impact of the 2015 VM policies on groups of 100 or more eligible professionals subject to the VM in CY 2015, including findings based on the data contained in the 2013 QRURs for all groups of physicians and solo practitioners.

14. Interim Revisions to the Electronic Health Record (EHR) Incentive Program

This interim final rule will allow us flexibility in setting the deadline for

significant hardship exception applications. We refer readers to the impact analyses included in the final rule titled “Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2” (77 FR 53698 through 54162) and Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs for 2014 and Other Changes to the EHR Incentive Program; and Health Information Technology; Revisions to the Certified EHR Technology Definition and EHR Certification Changes Related to Standards; Final Rule (79 FR 52911–52933).

G. Alternatives Considered

This final rule with comment period contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our final policies and, where relevant, alternatives that were considered.

H. Impact on Beneficiaries

There are a number of changes in this final rule with comment period that would have an effect on beneficiaries. In general, we believe that many of the changes, including the refinements of the PQRS with its focus on measuring, submitting, and analyzing quality data; establishing the basis for the value-based payment modifier to adjust physician payment beginning in CY 2015; improved accuracy in payment through revisions to the inputs used to calculate payments under the PFS; and revisions to payment for Part B drugs will have a positive impact and improve

the quality and value of care provided to Medicare beneficiaries.

Most of the aforementioned policy changes could result in a change in beneficiary liability as relates to coinsurance (which is 20 percent of the fee schedule amount if applicable for the particular provision after the beneficiary has met the deductible). To illustrate this point, as shown in Table 94, the CY 2014 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) is \$108.18, which means that in CY 2014 a beneficiary would be responsible for 20 percent of this amount, or \$21.64. Based on this final rule with comment period, using the January 1–March 31, 2015 CF of 35.8013, the CY 2015 national payment amount in the nonfacility setting for CPT code 99203, as shown in Table 94, is \$109.19, which means that, in CY 2015, the beneficiary coinsurance for this service would be \$21.84. In addition, we are finalizing a change in our definition of colorectal cancer screening test. As a result, beneficiary liability will not be applied to anesthesia billed in conjunction with a colorectal cancer screening test.

I. Accounting Statement

As required by OMB Circular A–4 (available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>), in Table 99 (Accounting Statement), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2014 to CY 2015 based on the FY 2015 President’s Budget baseline. Note that subsequent legislation changed the updates for 2015 from those shown in the 2015 President’s Budget baseline.

TABLE 99: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
CY 2015 Annualized Monetized Transfers	Estimated decrease in expenditures of \$14.7 billion for PFS conversion factor update.

TABLE 99: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES—Continued

Category	Transfers
From Whom to Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.
CY 2015 Annualized Monetized Transfers	Estimated increase in payment of \$234 million.
From Whom to Whom?	Federal Government to eligible professionals who satisfactorily participate in the Physician Quality Reporting System (PQRS).

TABLE 100: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS

Category	Transfer
CY 2015 Annualized Monetized Transfers of beneficiary cost coinsurance.	\$9 million.
From Whom to Whom?	Beneficiaries to Federal Government.

J. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provides an initial “Regulatory Flexibility Analysis.” The previous analysis, together with the preceding portion of this preamble, provides a Regulatory Impact Analysis.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 403

Grant programs—health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Kidney diseases, Medicare, Physician Referral, Reporting and recordkeeping requirements.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Electronic health records, Health facilities, Health professions, Health maintenance organizations (HMO), Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:—

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 1. The authority citation for part 403 continues to read as follows:

Authority: 42 U.S.C. 1395b–3 and Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 403.902 [Amended]

■ 2. In § 403.902, remove the definition of “Covered device”.

■ 3. Section 403.904 is amended by—
 ■ A. Revising paragraphs (c)(8), (d)(3), and (d)(4).

■ B. Adding paragraphs (d)(5) and (d)(6).

■ C. Revising paragraph (f)(1)(iv).

■ D. Removing paragraph (g).

■ E. Redesignating paragraphs (h) and (i) as paragraphs (g) and (h), respectively.

■ F. Amending newly redesignated paragraph (h)(2)(ii) by removing “paragraph (i)(2)(i) of this section” and adding in its place “paragraph (h)(2)(i) of this section”.

■ G. Amending newly redesignated paragraph (h)(2)(iii) by removing “paragraph (i)(2)(ii) of this section” and adding in its place “paragraph (h)(2)(i) of this section”.

The revisions and additions read as follows:

§ 403.904 Reports of payments or other transfers of value to covered recipients.

* * * * *

(c) * * *

(8) *Related covered drug, device, biological or medical supply.* Report the marketed name of the related covered drugs, devices, biologicals, or medical supplies, and therapeutic area or product category unless the payment or other transfer of value is not related to a particular covered drug, device, biological or medical supply.

(i) For drugs and biologicals, if the marketed name has not yet been selected, applicable manufacturers must indicate the name registered on *clinicaltrials.gov*.

(ii) Applicable manufacturers may report the marketed name and therapeutic area or product category for payments or other transfers of value related to a non-covered drug, device, biological, or medical supply.

(iii) Applicable manufacturers must indicate if the related drug, device, biological, or medical supply is covered or non-covered.

(iv) Applicable manufacturers must indicate if the payment or other transfer

of value is not related to any covered or non-covered drug, device, biological or medical supply.

* * * * *

(d) * * *

(3) Stock.

(4) Stock option.

(5) Any other ownership interest.

(6) Dividend, profit or other return on investment.

* * * * *

(f) * * *

(1) * * *

(iv) Name(s) of any related covered drugs, devices, biologicals, or medical supplies (subject to the requirements specified in paragraph (c)(8) of this section), for drugs and biologicals, the relevant National Drug Code(s), if any, for devices and medical supplies and report a therapeutic area or product category if a marketed name is not available.

* * * * *

§ 403.906 [Amended]

■ 4. In § 403.906, amend paragraph (b)(6) by removing “§ 403.904(c) through (i)” and by adding in its place “§ 403.904(c) through (h).”

■ 5. New subpart K is added to part 403 to read as follows:

Subpart K—Access to Identifiable Data for the Center for Medicare and Medicaid Models

Sec.

403.1100 Purpose and scope.

403.1105 Definitions.

403.1110 Evaluation of models.

Subpart K—Access to Identifiable Data for the Center for Medicare and Medicaid Models

§ 403.1100 Purpose and scope.

The regulations in this subpart implement section 1115A of the Act. The intent of that section is to enable CMS to test innovative payment and service delivery models to reduce program expenditures while preserving and/or enhancing the quality of care furnished to individuals under titles XVIII, XIX, and XXI of the Act. The Secretary is also required to conduct an evaluation of each model tested.

§ 403.1105 Definitions.

For purposes of this subpart—
Applicable titles means Titles XVIII, XIX, or XXI of the Act.

§ 403.1110 Evaluation of models.

(a) *Evaluation*. The Secretary conducts an evaluation of each model tested under section 1115A of the Act. Such evaluation must include an analysis of the following:

(1) The quality of care furnished under the model, including the

measurement of patient-level outcomes and patient-centeredness criteria determined appropriate by the Secretary.

(2) The changes in spending under the applicable titles by reason of the model.

(b) *Information*. Any State or other entity participating in the testing of a model under section 1115A of the Act must collect and report such information, including “protected health information” as that term is defined at 45 CFR 160.103, as the Secretary determines is necessary to monitor and evaluate such model. Such data must be produced to the Secretary at the time and in the form and manner specified by the Secretary.

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 6. The authority citation for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 7. Section 405.400 is amended by revising the definition of “Emergency care services” to read as follows:

§ 405.400 Definitions.

* * * * *

Emergency care services means inpatient or outpatient hospital services that are necessary to prevent death or serious impairment of health and, because of the danger to life or health, require use of the most accessible hospital available and equipped to furnish those services.

* * * * *

§ 405.420 [Amended]

■ 8. In § 405.420, amend paragraph (e), by removing the phrase “Medicare+Choice” and adding in its place the phrase “Medicare Advantage”.

§ 405.425 [Amended]

■ 9. In § 405.425, amend paragraph (a) by removing the phrase “Medicare+Choice” and adding in its place the phrase “Medicare Advantage”.

§ 405.450 [Amended]

■ 10. In § 405.450, amend paragraph (a) by removing the reference “§ 405.803” and adding in its place the reference “§ 498.3(b) of this chapter” and amend paragraph (b) by removing the reference “§ 405.803” and adding in its place “§ 405.924”.

§ 405.455 [Amended]

■ 11. In § 405.455, remove the phrase “Medicare+Choice” and add in its place the phrase “Medicare Advantage” wherever it appears.

■ 12. Section 405.924 is amended by adding paragraph (b)(15) to read as follows:

§ 405.924 Actions that are initial determinations.

* * * * *

(b) * * *

(15) A claim not payable to a beneficiary for the services of a physician who has opted-out.

* * * * *

■ 13. Section 405.2413 is amended by—

■ A. Amending paragraph (a)(4) by removing “;” and by adding in its place “; and”.

■ B. Revising paragraph (a)(5).

■ C. Removing paragraph (a)(6).

The revision reads as follow:

§ 405.2413 Services and supplies incident to a physician’s services.

(a) * * *

(5) Furnished under the direct supervision of a physician.

* * * * *

■ 14. Section 405.2415 is amended by—

■ A. Revising the section heading and paragraph (a)(5).

■ B. Removing paragraph (a)(6).

The revision reads as follows:

§ 405.2415 Services and supplies incident to nurse practitioner, physician assistant, or certified nurse-midwife services.

(a) * * *

(5) Furnished under the direct supervision of a nurse practitioner, physician assistant, or certified nurse-midwife.

* * * * *

■ 15. Section 405.2452 is amended by—

■ A. Amending paragraph (a)(4) by removing “;” and by adding in its place “; and”.

■ B. Revising paragraph (a)(5).

■ C. Removing paragraph (a)(6).

The revision reads as follows:

§ 405.2452 Services and supplies incident to clinical psychologist and clinical social worker services.

(a) * * *

(5) Furnished under the direct supervision of a clinical psychologist or clinical social worker.

* * * * *

■ 16. Section 405.2463 is revised to read as follows:

§ 405.2463 What constitutes a visit.

(a) *Visit—General*. (1) For RHCs, a visit is either of the following:

(i) Face-to-face encounter between a RHC patient and one of the following:

- (A) Physician.
- (B) Physician assistant.
- (C) Nurse practitioner.

(D) Certified nurse midwife.
(E) Visiting registered professional or licensed practical nurse.

- (G) Clinical psychologist.
- (H) Clinical social worker.

(ii) Qualified transitional care management service.

(2) For FQHCs, a visit is either of the following:

(i) A visit as described in paragraph (a)(1)(i) or (ii) of this section.

(ii) A face-to-face encounter between a patient and either of the following:

(A) A qualified provider of medical nutrition therapy services as defined in part 410, subpart G, of this chapter.

(B) A qualified provider of outpatient diabetes self-management training services as defined in part 410, subpart H, of this chapter.

(b) *Visit—Medical.* (1) A medical visit is a face-to-face encounter between a RHC or FQHC patient and one of the following:

- (i) Physician.
- (ii) Physician assistant.
- (iii) Nurse practitioner.
- (iv) Certified nurse midwife.

(v) Visiting registered professional or licensed practical nurse.

(2) A medical visit for a FQHC patient may be either of the following:

- (i) Medical nutrition therapy visit.
- (ii) Diabetes outpatient self-management training visit.

(3) *Visit—Mental health.* A mental health visit is a face-to-face encounter between a RHC or FQHC patient and one of the following:

- (i) Clinical psychologist.
- (ii) Clinical social worker.
- (iii) Other RHC or FQHC practitioner, in accordance with paragraph (b)(1) of this section, for mental health services.

(c) *Visit—Multiple.* (1) For RHCs and FQHCs that are authorized to bill under the reasonable cost system, encounters with more than one health professional and multiple encounters with the same health professional that take place on the same day and at a single location constitute a single visit, except when the patient—

(i) Suffers an illness or injury subsequent to the first visit that requires additional diagnosis or treatment on the same day;

(ii) Has a medical visit and a mental health visit on the same day; or

(iii) Has an initial preventive physical exam visit and a separate medical or mental health visit on the same day.

(2) For RHCs and FQHCs that are authorized to bill under the reasonable

cost system, Medicare pays RHCs and FQHCs for more than 1 visit per day when the conditions in paragraph (c)(1) of this section are met.

(3) For FQHCs that are authorized to bill under the reasonable cost system, Medicare pays for more than 1 visit per day when a DSMT or MNT visit is furnished on the same day as a visit described in paragraph (c)(1) of this section are met.

(4) For FQHCs billing under the prospective payment system, Medicare pays for more than 1 visit per day when the patient—

(i) Suffers an illness or injury subsequent to the first visit that requires additional diagnosis or treatment on the same day; or

(ii) Has a medical visit and a mental health visit on the same day.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 17. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302, 1395m, 1395hh, and 1395ddd).

■ 18. Section 410.26 is amended by revising paragraphs (b)(5) and (b)(6) to read as follows:

§ 410.26 Services and supplies incident to a physician's professional services: Conditions.

* * * * *

(b) * * *

(5) In general, services and supplies must be furnished under the direct supervision of the physician (or other practitioner). Services and supplies furnished incident to transitional care management and chronic care management services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided by clinical staff. The physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based.

(6) Services and supplies must be furnished by the physician, practitioner with an incident to benefit, or auxiliary personnel.

* * * * *

■ 19. Section 410.37 is amended by revising paragraph (a)(1)(iii) to read as follows:

§ 410.37 Colorectal cancer screening tests: Conditions for and limitations on coverage.

(a) * * *

(1) * * *

(iii) Screening colonoscopies, including anesthesia furnished in conjunction with the service.

* * * * *

■ 20. Section 410.59 is amended by revising paragraph (c)(1)(ii) to read as follows:

§ 410.59 Outpatient occupational therapy services: Conditions.

* * * * *

(c) * * *

(1) * * *

(ii) Engage in the private practice of occupational therapy on a regular basis as an individual, in one of the following practice types: a solo practice, partnership, or group practice; or as an employee of one of these.

* * * * *

■ 21. Section 410.60 is amended by revising paragraph (c)(1)(ii) to read as follows:

§ 410.60 Outpatient physical therapy services: Conditions.

* * * * *

(c) * * *

(1) * * *

(ii) Engage in the private practice of physical therapy on a regular basis as an individual, in one of the following practice types: a solo practice, partnership, or group practice; or as an employee of one of these.

* * * * *

■ 22. Section 410.62 is amended by revising paragraph (c)(1)(ii) to read as follows:

§ 410.62 Outpatient speech-language pathology services: Conditions and exclusions.

* * * * *

(c) * * *

(1) * * *

(ii) Engage in the private practice of speech-language pathology on a regular basis as an individual, in one of the following practice types: a solo practice, partnership, or group practice; or as an employee of one of these.

* * * * *

■ 23. Section 410.78 is amended by revising paragraph (b) introductory text and paragraph (f) to read as follows:

§ 410.78 Telehealth services.

* * * * *

(b) *General rule.* Medicare Part B pays for covered telehealth services included on the telehealth list when furnished by an interactive telecommunications system if the following conditions are met:

* * * * *

(f) *Process for adding or deleting services.* Changes to the list of Medicare

telehealth services are made through the annual physician fee schedule rulemaking process. A list of the services covered as telehealth services under this section is available on the CMS Web site.

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 24. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn).

■ 25. Section 411.15 is amended by adding paragraph (p)(2)(xvii) to read as follows:

§ 411.15 Particular services excluded from coverage.

* * * * *

(p) * * *

(2) * * *

(xvii) Those RHC and FQHC services that are described in § 405.2411(b)(2) of this chapter.

* * * * *

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 26. The authority citation for part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), sec. 124 of Pub. L. 106–113 (113 Stat. 1501A–332), sec. 1206 of Pub. L. 113–67, and sec. 112 of Pub. L. 113–93.

§ 412.64 [Amended]

■ 27. In 412.64—

■ A. Amend paragraph (d)(4)(ii)(A) by removing the phrase “to April 1 of the year before the payment adjustment year” and adding in its place the phrase “to April 1 of the year before the payment adjustment year, or a later date specified by CMS”.

■ B. Amend paragraph (d)(4)(ii)(A) by removing the phrase “by April 1 of the year before the applicable payment adjustment year” and adding in its place the phrase “by April 1 of the year before the applicable payment adjustment year, or a later date specified by CMS”.

■ C. Amend paragraph (d)(4)(ii)(B)(1) by removing the phrase “April 1 of the year before the applicable payment adjustment year” and adding in its place the phrase “April 1 of the year before the applicable payment adjustment year, or a later date specified by CMS”.

■ D. Amend paragraph (d)(4)(ii)(B)(2) by removing the phrase “April 1 of the year

before the applicable payment adjustment year” and adding in its place the phrase “April 1 of the year before the applicable payment adjustment year, or a later date specified by CMS”.

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITY SERVICES

■ 28. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883 and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Pub. L. 106–113 (113 Stat. 1501A–332), sec. 3201 of Pub. L. 112–96 (126 Stat. 156), and sec. 632 of Pub. L. 112–240 (126 Stat. 2354).

§ 413.70 [Amended]

■ 29. Amend § 413.70 by:

■ A. Amending paragraph (a)(6)(ii) introductory text by removing the phrase “no later than November 30 after the close of the applicable EHR reporting period” and adding in its place the phrase “no later than November 30 after the close of the applicable EHR reporting period, or a later date specified by CMS”.

■ B. Amending paragraph (a)(6)(ii)(A) by removing the phrase “to November 30 after the end of the payment adjustment year” and adding in its place the phrase “to November 30 after the end of the payment adjustment year, or a later date specified by CMS”.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 30. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

■ 31. Section 414.24 is amended by—

■ A. Revising the section heading, and paragraphs (a) and (b).

■ B. Redesignating paragraph (c) as paragraph (d).

■ C. Adding new paragraph (c).

The revisions and addition read as follows:

§ 414.24 Publication of RVUs and direct PE inputs.

(a) **Definitions.** For purposes of this section, the following definitions apply:

Existing code means a code that is not a new code under paragraph (c)(2) of

this section, and includes codes for which the descriptor is revised and codes that are combinations or subdivisions of previously existing codes.

New code means a code that describes a service that was not previously described or valued under the PFS using any other code or combination of codes.

(b) *Revisions of RVUs and Direct PE Inputs.* For valuations for calendar year 2017 and beyond, CMS publishes, through notice and comment rulemaking in the **Federal Register** (including proposals in a proposed rule), changes in RVUs or direct PE inputs for existing codes.

(c) *Establishing RVUs and Direct PE inputs for new codes.*

(1) *General rule.* CMS establishes RVUs and direct PE inputs for new codes in the manner described in paragraph (b) of this section.

(2) *Exception for new codes for which CMS does not have sufficient information.* When CMS determines for a new code that it does not have sufficient information to include proposed RVUs or direct PE inputs in the proposed rule, but that it is in the public interest for Medicare to use a new code during a payment year, CMS will publish in the **Federal Register** RVUs and direct PE inputs that are applicable on an interim basis subject to public comment. After considering public comments and other information on interim RVUs and PE inputs for the new code, CMS publishes in the **Federal Register** the final RVUs and PE inputs for the code.

* * * * *

■ 32. Section 414.90 is amended by—

■ A. In paragraph (b) by revising the definition of “Measures group”.

■ B. In paragraphs (h)(5)(i)(B), (h)(5)(v), (j)(5)(i)(B) and (j)(5)(v) remove the phrase “CAHPS” and add in its place the phrase “CAHPS for PQRS”.

■ C. In paragraphs (h)(4)(v) and (j)(4)(vi) remove the phrase “CAHPS” and add in its place the phrase “CAHPS for PQRS”.

■ D. Redesignate paragraphs (j)(4) and (j)(5) as (j)(5) and (j)(6), respectively.

■ E. Adding new paragraphs (j)(4), (j)(7), (k)(4) and (m)(3).

■ F. Revising paragraph (m)(1).

The revisions read as follows:

§ 414.90 Physician Quality Reporting System (PQRS).

* * * * *

(b) * * *

Measures group means a subset of six or more PQRS measures that have a particular clinical condition or focus in common. The denominator definition and coding of the measures group identifies the condition or focus that is

shared across the measures within a particular measures group.

* * * * *

(j) * * *

(4) *Satisfactory Reporting Criteria for Individual Eligible Professionals for the 2017 PQRS Payment Adjustment.* An individual eligible professional who wishes to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Via Claims.* (A) For the 12-month 2017 PQRS payment adjustment reporting period—

(1)(i) Report at least 9 measures, covering at least 3 of the NQS domains and report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the 9 measures reported, if the eligible professional sees at least 1 Medicare patient in a face-to-face encounter, the eligible professional must report on at least 1 measure contained in the cross-cutting measure set specified by CMS. If less than 9 measures apply to the eligible professional, report up to 8 measures and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.

(ii) [Reserved]

(ii) *Via Qualified Registry.* (A) For the 12-month 2017 PQRS payment adjustment reporting period—

(1)(i) Report at least 9 measures, covering at least 3 of the NQS domains and report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the 9 measures reported, if the eligible professional sees at least 1 Medicare patient in a face-to-face encounter, the eligible professional must report on at least 1 measure contained in the cross-cutting measure set specified by CMS. If less than 9 measures apply to the eligible professional, report up to 8 measures and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies.

(ii) Report at least 1 measures group and report each measures group for at least 20 patients, a majority of which must be Medicare Part B FFS patients.

(2) Measures with a 0 percent performance rate or measures groups containing a measure with a 0 percent performance rate will not be counted.

(iii) *Via EHR Direct Product.* For the 12-month 2017 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the NQS domains. If an eligible professional's direct EHR product does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR Data Submission Vendor.* For the 12-month 2017 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the NQS domains. If an eligible professional's EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

* * * * *

(7) *Satisfactory reporting criteria for group practices for the 2017 PQRS payment adjustment.* A group practice who wishes to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Via the GPRO web interface.* For the 12-month 2017 PQRS payment adjustment reporting period, for a group practice of 25 to 99 eligible professionals, report on all measures included in the web interface and populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then report on 100 percent of assigned beneficiaries. A group practice must report on at least 1 measure for which there is Medicare patient data.

(ii) *Via Qualified Registry.* For a group practice of 2 to 99 eligible professionals, for the 12-month 2017 PQRS payment adjustment reporting period, report at least 9 measures, covering at least 3 of the NQS domains and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies; or if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, then the group practice must report up to 8 measures for which

there is Medicare patient data and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the measures reported, if any eligible professional in the group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice must report on at least 1 measure contained in the cross-cutting measure set specified by CMS. Measures with a 0 percent performance rate would not be counted; or

(iii) *Via EHR Direct Product.* For a group practice of 2 to 99 eligible professionals, for the 12-month 2017 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the NQS domains. If a group practice's direct EHR product does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR Data Submission Vendor.* For a group practice of 2 to 99 eligible professionals, for the 12-month 2017 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the NQS domains. If a group practice's EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(v) *Via a Certified Survey Vendor in addition to a Qualified Registry.* For a group practice of 2 or more eligible professionals, for the 12-month 2017 PQRS payment adjustment reporting period, report all CAHPS for PQRS survey measures via a CMS-certified survey vendor and report at least 6 additional measures covering at least 2 of the NQS domains using a qualified registry. If less than 6 measures apply to the group practice, the group practice must report up to 5 measures. Of the additional measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, if any eligible professional in the group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice must report on at least 1 measure in the cross-cutting measure set specified by CMS.

(vi) *Via a Certified Survey Vendor in addition a Direct EHR Product or EHR Data Submission Vendor.* For a group practice of 2 or more eligible

professionals, for the 12-month 2017 PQRS payment adjustment reporting period, report all CAHPS for PQRS survey measures via a CMS-certified survey vendor and report at least 6 additional measures, outside of CAHPS for PQRS, covering at least 2 of the NQS domains using the direct EHR product that is CEHRT or EHR data submission vendor product that is CEHRT. If less than 6 measures apply to the group practice, the group practice must report up to 5 measures. Of the additional measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, the group practice must report on at least 1 measure for which there is Medicare patient data.

(vii) *Via a Certified Survey Vendor in addition to the GPRO Web interface.* (A) For a group practice of 25 or more eligible professionals, for the 12-month 2017 PQRS payment adjustment reporting period, report all CAHPS for PQRS survey measures via a CMS-certified survey vendor and report on all measures included in the GPRO web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice would report on 100 percent of assigned beneficiaries. A group practice must report on at least 1 measure for which there is Medicare patient data.

(B) [Reserved]

(k) * * *

(4) *Satisfactory participation criteria for individual eligible professionals for the 2017 PQRS payment adjustment.* An individual eligible professional who wishes to meet the criteria for satisfactory participation in a QCDR for the 2017 PQRS payment adjustment must report information on quality measures identified by the QCDR in one of the following manner:

(i) For the 12-month 2017 PQRS payment adjustment reporting period, report at least 9 measures available for reporting under a QCDR covering at least 3 of the NQS domains, and report each measure for at least 50 percent of the eligible professional's patients. Of these measures, report on at least 2 outcome measures, or, if 2 outcomes measures are not available, report on at least 2 outcome measures and at least 1 of the following types of measures—resource use, patient experience of care, efficiency/appropriate use or patient safety.

(ii) [Reserved]

* * * * *

(m) * * *

(1) To request an informal review for reporting periods that occur prior to 2014, an eligible professional or group practice must submit a request to CMS within 90 days of the release of the feedback reports. To request an informal review for reporting periods that occur in 2014 and subsequent years, an eligible professional or group practice must submit a request to CMS within 60 days of the release of the feedback reports. The request must be submitted in writing and summarize the concern(s) and reasons for requesting an informal review and may also include information to assist in the review.

* * * * *

(3) If, during the informal review process, CMS finds errors in data that was submitted by a third-party vendor on behalf of an eligible professional or group practice using either the qualified registry, EHR data submission vendor, or QCDR reporting mechanisms, CMS may allow for the resubmission of data to correct these errors.

(i) CMS will not allow resubmission of data submitted via claims, direct EHR, and the GPRO web interface reporting mechanisms.

(ii) CMS will only allow resubmission of data that was already previously submitted to CMS.

(iii) CMS will only accept data that was previously submitted for the reporting periods for which the corresponding informal review period applies.

* * * * *

§ 414.511 [Removed]

■ 33. Section § 414.511 is removed.

■ 34. Section 414.610 is amended by revising paragraphs (c)(1)(ii) introductory text and (c)(5)(ii) to read as follows:

§ 414.610 Basis of payment.

* * * * *

(c) * * *

(1) * * *

(ii) For services furnished during the period July 1, 2008 through March 31, 2015, ambulance services originating in:

* * * * *

(5) * * *

(ii) For services furnished during the period July 1, 2004 through March 31, 2015, the payment amount for the ground ambulance base rate is increased by 22.6 percent where the point of pickup is in a rural area determined to be in the lowest 25 percent of rural population arrayed by population density. The amount of this increase is based on CMS's estimate of the ratio of the average cost per trip for the rural

areas in the lowest quartile of population compared to the average cost per trip for the rural areas in the highest quartile of population. In making this estimate, CMS may use data provided by the GAO.

* * * * *

■ 35. Section 414.1200 is amended by revising paragraphs (a) and (b)(5) to read as follows:

§ 414.1200 Basis and scope.

(a) *Basis.* This subpart implements section 1848(p) of the Act by establishing a payment modifier that provides for differential payment starting in 2015 to a group of physicians and starting in 2017 to a group and a solo practitioner under the Medicare Physician Fee Schedule based on the quality of care furnished compared to cost during a performance period.

(b) * * *

(5) Additional measures for groups and solo practitioners.

* * * * *

■ 36. Section 414.1205 is amended by—

■ A. Revising the definitions of “Group of physicians” and “Value-based payment modifier.”

■ B. Adding the definition of “Solo practitioner” in alphabetical order.

The addition and revisions read as follows:

§ 414.1205 Definitions.

* * * * *

Group of physicians (Group) means a single Taxpayer Identification Number (TIN) with 2 or more eligible professionals, as identified by their individual National Provider Identifier (NPI), who have reassigned their Medicare billing rights to the TIN.

* * * * *

Solo practitioner means a single Taxpayer Identification Number (TIN) with one eligible professional who is identified by an individual National Provider Identifier (NPI) billing under the TIN.

* * * * *

Value-based payment modifier means the percentage as determined under § 414.1270 by which amounts paid to a group or solo practitioner under the Medicare Physician Fee Schedule established under section 1848 of the Act are adjusted based upon a comparison of the quality of care furnished to cost as determined by this subpart.

■ 37. Section 414.1210 is amended by—

■ A. Adding paragraphs (a)(3), (a)(4), (b)(2), (b)(3), and (b)(4).

■ B. Revising paragraph (c).

The additions and revision reads as follows:

§ 414.1210 Application of the value-based payment modifier.

(a) * * *

(3) For the CY 2017 payment adjustment period and each subsequent calendar year payment adjustment period, to physicians in groups with 2 or more eligible professionals and to physicians who are solo practitioners based on the performance period for the payment adjustment period as described at § 414.1215.

(4) For the CY 2018 payment adjustment period and each subsequent calendar year payment adjustment period, to nonphysician eligible professionals in groups with 2 or more eligible professionals and to nonphysician eligible professionals who are solo practitioners based on the performance period for the payment adjustment period as described at § 414.1215.

(b) * * *

(2) *Application of the value-based payment modifier to participants in the Shared Savings Program.*

(i) For the CY 2017 payment adjustment period and each subsequent calendar year payment adjustment period, the value-based payment modifier is applicable to physicians in groups with 2 or more eligible professionals and to physicians who are solo practitioners that participate in an ACO under the Shared Savings Program during the performance period for the payment adjustment period as described at § 414.1215. The value-based payment modifier for a group or solo practitioner that participates in an ACO under the Shared Savings Program during the performance period is determined based on paragraphs (b)(2)(i)(A) through (D) of this section.

(A) The cost composite is classified as “average” under § 414.1275(b).

(B) The quality composite score is calculated under § 414.1260(a) using quality data reported by the ACO for the performance period through the ACO GPRO Web interface as required under § 425.504(a)(1) or another mechanism specified by CMS and the ACO all-cause readmission measure.

(C) For the CY 2017 payment adjustment period, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275 for the payment adjustment period, except that if the ACO does not successfully report quality data as described in paragraph (b)(2)(i)(B) of this section for the performance period, such adjustment will be equal to –4% for groups with 10 or more eligible professionals and equal to –2% for groups with two to nine eligible professionals and for solo practitioners.

(D) The same value-based payment modifier adjustment will be applied in the payment adjustment period to all groups based on size as specified under § 414.1275 and solo practitioners that participated in the ACO during the performance period.

(ii) For the CY 2018 payment adjustment period and each subsequent calendar year payment adjustment period, the value-based payment modifier is applicable to nonphysician eligible professionals in groups with 2 or more eligible professionals and to nonphysician eligible professionals who are solo practitioners that participate in an ACO under the Shared Savings Program during the performance period for the payment adjustment period as described at § 414.1215. The value-based payment modifier for nonphysician eligible professionals is determined in the same manner as for physicians as described under paragraphs (b)(2)(i)(A) through (D) of this section.

(3) *Application of the value-based payment modifier to participants in the Pioneer ACO Model and the Comprehensive Primary Care Initiative.*

(i) For the CY 2017 payment adjustment period, the value-based payment modifier is applicable to physicians in groups with 2 or more eligible professionals and to physicians who are solo practitioners that participate in the Pioneer ACO Model or the Comprehensive Primary Care (CPC) Initiative during the performance period for the payment adjustment period as described at § 414.1215. For purposes of the value-based payment modifier, a group or solo practitioner is considered to be participating in the Pioneer ACO Model or CPC Initiative if at least one eligible professional billing under the TIN in the performance period is participating in the Pioneer ACO Model or CPC Initiative during the performance period. The value-based payment modifier for groups and solo practitioners that participate in the Pioneer ACO Model or the CPC Initiative during the performance period is determined based on paragraphs (b)(3)(i)(A) through (C) of this section.

(A) The cost composite is classified as “average” under § 414.1275(b).

(B) The quality composite is classified as “average” under § 414.1275(b).

(C) The same value-based payment modifier adjustment will be applied in the payment adjustment period to all groups based on size as specified under § 414.1275 and solo practitioners that participated in the Pioneer ACO or CPC site during the performance period.

(4) *Application of the value-based payment modifier to participants in*

other similar Innovation Center models or CMS initiatives.

(i) For the CY 2017 payment adjustment period and each subsequent calendar year payment adjustment period, the value-based payment modifier is applicable to physicians in groups with 2 or more eligible professionals and to physicians who are solo practitioners that participate in other similar Innovation Center models or CMS initiatives during the performance period for the payment adjustment period as described at § 414.1215. For purposes of the value-based payment modifier, a group or solo practitioner is considered to be participating in a similar Innovation Center model or CMS initiative if at least one eligible professional billing under the TIN in the performance period is participating in the model or initiative in the performance period. The value-based payment modifier for groups and solo practitioners that participate in a similar Innovation Center model or CMS initiative is determined based on paragraphs (b)(3)(i)(A) through (C) of this section.

(ii) [Reserved]

(c) *Group size determination.* The list of groups of physicians subject to the value-based payment modifier for the CY 2015 payment adjustment period is based on a query of PECOS on October 15, 2013. For each subsequent calendar year payment adjustment period, the list of groups and solo practitioners subject to the value-based payment modifier is based on a query of PECOS that occurs within 10 days of the close of the Physician Quality Reporting System group registration process during the applicable performance period described at § 414.1215. Groups are removed from the PECOS-generated list if, based on a claims analysis, the group did not have the required number of eligible professionals, as defined in § 414.1210(a), that submitted claims during the performance period for the applicable calendar year payment adjustment period. Solo practitioners are removed from the PECOS-generated list if, based on a claims analysis, the solo practitioner did not submit claims during the performance period for the applicable calendar year payment adjustment period.

§ 414.1220 [Amended]

■ 38. In § 414.1220, remove the phrase “Groups of physicians” and add in its place the phrase “Solo practitioners and groups”.

■ 39. Section 414.1225 is revised to read as follows:

§ 414.1225 Alignment of Physician Quality Reporting System quality measures and quality measures for the value-based payment modifier.

All of the quality measures for which solo practitioners and groups (or individual eligible professionals within such groups) are eligible to report under the Physician Quality Reporting System in a given calendar year are used to calculate the value-based payment modifier for the applicable payment adjustment period, as defined in § 414.1215, to the extent a solo practitioner or a group (or individual eligible professionals within such group) submit data on such measures.

■ 40. Section 414.1230 is amended by revising the section heading and the introductory text to read as follows:

§ 414.1230 Additional measures for groups and solo practitioners.

The value-based payment modifier includes the following additional quality measures (outcome measures) as applicable for all groups and solo practitioners subject to the value-based payment modifier:

* * * * *

§ 414.1235 [Amended]

■ 41. In § 414.1235, amend paragraph (a) introductory text, by removing the phrase “of physicians subject” and add in its place the phrase “and solo practitioners subject”.

■ 42. Section 414.1240 is revised to read as follows:

§ 414.1240 Attribution for quality of care and cost measures.

(a) Beneficiaries are attributed to groups and solo practitioners subject to the value-based payment modifier using a method generally consistent with the method of assignment of beneficiaries under § 425.402 of this chapter, for measures other than the Medicare Spending per Beneficiary measure.

(b) For the Medicare Spending per Beneficiary (MSPB) measure, an MSPB episode is attributed to the group or the solo practitioner subject to the value-based payment modifier whose eligible professionals submitted the plurality of claims (as measured by allowable charges) under the group's or solo practitioner's TIN for Medicare Part B services, rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the applicable performance period described at § 414.1215.

§ 414.1245 [Amended]

■ 43. In § 414.1245, amend the introductory text, by removing the phrase “of physicians subject” and add

in its place the phrase “and solo practitioner subject”.

■ 44. Section 414.1250 is revised to read as follows:

§ 414.1250 Benchmarks for quality of care measures.

(a) The benchmark for quality of care measures reported through the PQRS using the claims, registries, EHR, or web interface is the national mean for that measure's performance rate (regardless of the reporting mechanism) during the year prior to the performance period. In calculating the national benchmark, solo practitioners' and groups' (or individual eligible professionals' within such groups) performance rates are weighted by the number of beneficiaries used to calculate the solo practitioners' or groups' (or individual eligible professionals' within such groups) performance rate.

(b) The benchmark for each outcome measure under § 414.1230, is the national mean for that measure's performance rate during the year prior to the performance period. In calculating the national benchmark, solo practitioners' and groups' (or individual eligible professionals' within such groups) performance rates are weighted by the number of beneficiaries used to calculate the solo practitioners' or groups' (or individual eligible professionals' within such groups) performance rate.

■ 45. Section 414.1255 is amended by revising paragraphs (b) and (c) to read as follows:

§ 414.1255 Benchmarks for cost measures.

* * * * *

(b) Beginning with the CY 2016 payment adjustment period, the cost measures of a group and solo practitioner subject to the value-based payment modifier are adjusted to account for the group's and solo practitioner's specialty mix, by computing the weighted average of the national specialty-specific expected costs. Each national specialty-specific expected cost is weighted by the proportion of each specialty in the group, the number of eligible professionals of each specialty in the group, and the number of beneficiaries attributed to the group.

(c) The national specialty-specific expected costs referenced in paragraph (b) of this section are derived by calculating, for each specialty, the average cost of beneficiaries attributed to groups and solo practitioners that include that specialty.

■ 46. Section 414.1265 is amended by revising the introductory text and paragraph (a) to read as follows:

§ 414.1265 Reliability of measures.

To calculate a composite score for a quality measure or a cost measure, a group or solo practitioner subject to the value-based payment modifier must have 20 or more cases for that measure.

(a) In a performance period, if a group or solo practitioner has fewer than 20 cases for a measure, that measure is excluded from its domain and the remaining measures in the domain are given equal weight.

(1) Starting with the CY 2017 payment adjustment period, the exception to this paragraph (a) is the all-cause hospital readmissions measure described at § 414.1230(c). In a performance period, if a group or a solo practitioner has fewer than 200 cases for this all-cause hospital readmissions measure, that measure is excluded from its domain and the remaining measures in the domain are given equal weight.

(2) [Reserved]

* * * * *

■ 47. Section 414.1270 is amended by revising paragraph (b)(4) and adding paragraph (c) to read as follows:

§ 414.1270 Determination and calculation of Value-Based Payment Modifier adjustments.

* * * * *

(b) * * *

(4) If at least fifty percent of the eligible professionals in the group meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2016 as specified by CMS, and all of those eligible professionals use a qualified clinical data registry and CMS is unable to receive quality performance data for them, the quality composite score for such group will be classified as “average” under § 414.1275(b)(1).

* * * * *

(c) For the CY 2017 payment adjustment period:

(1) A downward payment adjustment of –2.0 percent will be applied to a group with two to nine eligible professionals and a solo practitioner and a downward payment adjustment of –4.0 percent will be applied to a group with 10 or more eligible professionals subject to the value-based payment modifier if, during the applicable performance period as defined in § 414.1215, the following apply:

(i) Such group does not self-nominate for the PQRS GPRO and meet the criteria as a group to avoid the PQRS payment adjustment for CY 2017 as specified by CMS; and

(ii) Fifty percent of the eligible professionals in such group do not meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2017 as specified by CMS; or

(iii) Such solo practitioner does not meet the criteria as an individual to avoid the PQRS payment adjustment for CY 2017 as specified by CMS.

(2) For a group comprised of 10 or more eligible professionals that is not included in paragraph (c)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275(c)(3)(i).

(3) For a group comprised of between two to nine eligible professionals and a solo practitioner that are not included in paragraph (c)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275(c)(3)(ii).

(4) If at least fifty percent of the eligible professionals in the group meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2017 as specified by CMS, and all of those eligible professionals use a qualified clinical data registry and CMS is unable to receive quality performance data for them, the quality composite score for such group will be classified as “average” under § 414.1275(b)(1).

(5) A group and a solo practitioner subject to the value-based payment modifier will receive a cost composite score that is classified as “average” under § 414.1275(b)(2) if such group and solo practitioner do not have at least one cost measure with at least 20 cases.

■ 48. Section 414.1275 is amended by—

■ A. Revising paragraph (a).

■ B. Redesignating paragraphs (d) introductory text, (d)(1), and (d)(2) as

paragraphs (d)(1) introductory text, (d)(1)(i), and (d)(1)(ii), respectively.

■ C. Adding paragraphs (c)(3) and (d)(2). The revision and additions read as follows:

§ 414.1275 Value-based payment modifier quality-tiering scoring methodology.

(a) The value-based payment modifier amount for a group and a solo practitioner subject to the value-based payment modifier is based upon a comparison of the composite of quality of care measures and a composite of cost measures.

* * * * *

(c) * * * (3) The following value-based payment modifier percentages apply to the CY 2017 payment adjustment period:

(i) For groups with 10 or more eligible professionals:

CY 2017 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR GROUPS WITH 10 OR MORE ELIGIBLE PROFESSIONALS

Cost/quality	Low quality	Average quality	High quality
Low Cost	+0.0%	* +2.0x	* +4.0x
Average Cost	– 2.0%	+0.0%	* +2.0x
High Cost	– 4.0%	– 2.0%	+0.0%

* Groups eligible for an additional +1.0x if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where ‘x’ represents the upward payment adjustment factor.

(ii) For groups with two to nine eligible professionals and solo practitioners:

CY 2017 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR GROUPS WITH TWO TO NINE ELIGIBLE PROFESSIONALS AND SOLO PRACTITIONERS

Cost/quality	Low quality	Average quality	High quality
Low Cost	+0.0%	* +1.0x	* +2.0x
Average Cost	+0.0%	+0.0%	* +1.0x
High Cost	+0.0%	+0.0%	+0.0%

* Groups and solo practitioners eligible for an additional +1.0x if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where ‘x’ represents the upward payment adjustment factor.

(d) * * *

(2) Groups and solo practitioners subject to the value-based payment modifier that have an attributed beneficiary population with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide and for the CY 2017 payment adjustment period are subject to the quality-tiering approach, receive a greater upward payment adjustment as follows:

(i) Classified as high quality/low cost receive an upward adjustment of +5x (rather than +4x) if the group has 10 or more eligible professionals or +3x (rather than +2x) if a solo practitioner or

the group has two to nine eligible professionals; and

(ii) Classified as either high quality/average cost or average quality/low cost receive an upward adjustment of +3x (rather than +2x) if the group has 10 or more eligible professionals or +2x (rather than +1x) if a solo practitioner or the group has two to nine eligible professionals.

§ 414.1285 [Amended]

■ 49. In § 414.1285, remove the phrase “of physicians may” and add in its place the phrase “and a solo practitioner may”.

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 50. The authority citation for part 425 continues to read as follows:

Authority: Secs. 1102, 1106, 1871, and 1899 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 51. Section 425.308 is amended by revising paragraph (e) to read as follows:

§ 425.308 Public reporting and transparency.

* * * * *

(e) *Results of claims based measures.* All quality measures will be reported on Physician Compare in the same way as

for the group practices that report under the Physician Quality Reporting System.

■ 52. Section 425.502 is amended by—

■ A. In paragraph (a)(1), removing the phrase “of an ACO’s agreement, CMS” and adding in its place the phrase “of an ACO’s first agreement period, CMS”

■ B. In paragraph (b)(2)(ii), removing the phrase “80.00 percent.” and adding in its place the phrase “80.00 percent, or when the 90th percentile is equal to or greater than 95 percent.”

■ C. Revising paragraph (a)(2).

■ D. Adding paragraphs (a)(3), (a)(4), (b)(4), and (e)(4).

The revision and additions read as follows:

§ 425.502 Calculating the ACO quality performance score.

(a) * * *

(2) During subsequent performance years of the ACO’s first agreement period, the quality performance standard will be phased in such that the ACO must continue to report all measures but the ACO will be assessed on performance based on the quality performance benchmark and minimum attainment level of certain measures.

(3) Under the quality performance standard for each performance year of an ACO’s subsequent agreement period, the ACO must continue to report on all measures but the ACO will be assessed on performance based on the quality performance benchmark and minimum attainment level of certain measures.

(4) The quality performance standard for a newly introduced measure is set at the level of complete and accurate reporting for the first two reporting periods for which reporting of the measure is required. For subsequent reporting periods, the quality performance standard for the measure will be assessed according to the phase-in schedule for the measure.

(b) * * *

(4)(i) CMS will update the quality performance benchmarks every 2 years.

(ii) For newly introduced measures that transition to pay for performance in the second year of the 2-year benchmarking cycle, the benchmark will be established for that year and updated along with the other measures at the start of the next 2-year benchmarking cycle.

(iii) CMS will use up to three years of data, as available, to set the benchmark for each quality measure.

* * * * *

(e) * * *

(4)(i) ACOs that demonstrate quality improvement on established quality measures from year to year will be eligible for up to 4 bonus points per domain.

(ii) Bonus points are awarded based on an ACO’s net improvement in measures within a domain, which is calculated by determining the total number of significantly improved measures and subtracting the total number of significantly declined measures.

(iii) Up to four bonus points are awarded based on a comparison of the ACO’s net improvement in performance on the measures for the domain to the total number of individual measures in the domain.

(iv) When bonus points are added to points earned for the quality measures in the domain, the total points received for the domain may not exceed the maximum total points for the domain in the absence of the quality improvement measure.

(v) If an ACO renews its participation agreement for a subsequent agreement period, quality improvement will be measured based on a comparison between performance in the first year of the new agreement period and performance in the third year of the previous agreement period.

■ 53. Section 425.506 is amended by revising the section heading and adding paragraph (d) to read as follows:

§ 425.506 Incorporating reporting requirements related to adoption of Electronic health records technology.

* * * * *

(d) Eligible professionals participating in an ACO under the Shared Savings Program satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program when the following occurs:

(1) The eligible professional extracts data necessary for the ACO to satisfy the quality reporting requirements under this subpart from certified EHR technology.

(2) The ACO reports the ACO GPRO measures through a CMS web interface.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 54. The authority citation for part 489 continues to read as follows:

Authority: Secs. 1102, 1128I and 1871 of the Social Security Act (42 U.S.C. 1302, 1320a-7j, and 1395hh).

■ 55. Section 489.20 is amended by adding paragraph (s)(17) to read as follows:

§ 489.20 Basic commitments.

* * * * *

(s) * * *

(17) Those RHC and FQHC services that are described in § 405.2411(b)(2) of this chapter.

* * * * *

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 56. The authority citation for part 495 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 495.102 [Amended]

■ 57. In 495.102—

■ A. Amend paragraph (d)(4)(i) by removing the phrase in the first sentence “to July 1 of the year preceding the payment adjustment year” and adding in its place the phrase “to July 1 of the year preceding the payment adjustment year, or a later date specified by CMS”.

■ B. Amend paragraph (d)(4)(i) by removing the phrase in the second sentence “no later than July 1 of the year before the applicable payment adjustment year” and adding in its place the phrase “no later than July 1 of the year before the applicable payment adjustment year, or a later date specified by CMS”.

■ C. Amend paragraph (d)(4)(iii)(A) by removing the phrase in the second sentence “no later than July 1 of the year before the applicable payment adjustment year” and adding in its place the phrase “no later than July 1 of the year before the applicable payment adjustment year, or a later date specified by CMS”.

■ D. Amend paragraph (d)(4)(iii)(B) by removing the phrase in the second sentence “by July 1 of the year before the applicable payment adjustment year” and adding in its place the phrase “by July 1 of the year before the applicable payment adjustment year, or a later date specified by CMS”.

■ E. Amend the introductory text of paragraph (d)(4)(iv) introductory text by removing the phrase “by July 1 of the year before the applicable payment adjustment year” and adding in its place the phrase “by July 1 of the year before the applicable payment adjustment year, or a later date specified by CMS”.

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/IID AND CERTAIN NFs IN THE MEDICAID PROGRAM

■ 58. The authority citation for part 498 continues to read as follows:

Authority: Secs. 1102, 1128I and 1871 of the Social Security Act (42 U.S.C. 1302, 1320a-7j, and 1395hh).

■ 59. Section 498.3 is amended by adding paragraph (b)(19) to read as follow:

§ 498.3 Scope and applicability.

* * * * *

(b) * * *
(19) Whether a physician or practitioner has failed to properly opt-out, failed to maintain opt-out, failed to timely renew opt-out, failed to privately contract, or failed to properly terminate opt-out.

* * * * *

Dated: October 22, 2014.

Marilyn Tavenner,
Administrator, Centers for Medicare & Medicaid Services.

Dated: October 28, 2014.

Sylvia M. Burwell,
Secretary, Department of Health and Human Services.

[FR Doc. 2014-26183 Filed 10-31-14; 4:15 pm]

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Part III

Environmental Protection Agency

40 CFR Part 63

NESHAP Risk and Technology Review for the Mineral Wool and Wool
Fiberglass Industries; NESHAP for Wool Fiberglass Area Sources;
Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA-HQ-OAR-2010-1041 and EPA-HQ-OAR-2010-1042; FRL-9918-22-OAR]

RIN 2060-AQ90

NESHAP Risk and Technology Review for the Mineral Wool and Wool Fiberglass Industries; NESHAP for Wool Fiberglass Area Sources

AGENCY: Environmental Protection Agency.

ACTION: Supplemental notice of proposed rulemaking; Notice of public hearing.

SUMMARY: This action proposes amendments in addition to those proposed on November 25, 2011, and April 15, 2013, for the Mineral Wool Production and Wool Fiberglass Manufacturing source categories. This action addresses comments received on previous proposals, explains changes to previously proposed limits for sources in these industries and clarifies our use of the upper prediction limit (UPL) in setting MACT floors. The Environmental Protection Agency (EPA) is taking comments on only aspects of the proposed rules that are discussed in this document. When finalized, these proposed standards would increase the level of environmental protection.

DATES: *Comments.* Comments must be received on or before December 15, 2014. Under the Paperwork Reduction Act, comments on the information collection provisions are best assured of having full effect if the Office of Management and Budget (OMB) receives a copy of your comments on or before December 15, 2014.

Public Hearing. If anyone contacts the EPA requesting a public hearing by November 18, 2014, we will hold a public hearing on November 28, 2014 at 109 T.W. Alexander Drive, Research Triangle Park, NC.

ADDRESSES: Submit your comments on the proposed Mineral Wool risk and technology review (RTR) amendments, identified by EPA-HQ-OAR-2010-1041; or the wool fiberglass area source rule and the major source Wool Fiberglass RTR amendments, identified by Docket ID Number EPA-HQ-OAR-2010-1042; by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- *E-Mail:* A-and-R-Docket@epa.gov. Include Attention Docket ID No. EPA-HQ-OAR-2010-1041 or EPA-HQ-

OAR-2010-1042 in the subject line of the message.

- *Fax:* (202) 566-9744, Attention Docket ID No. EPA-HQ-OAR-2010-1041 or EPA-HQ-OAR-2010-1042.
- *Mail:* Environmental Protection Agency, EPA Docket Center (EPA/DC), Mail Code 28221T, Attention Docket ID No. EPA-HQ-OAR-2010-1041 or EPA-HQ-OAR-2010-1042, 1200 Pennsylvania Avenue NW., Washington, DC 20460. Please include a total of two copies. In addition, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: Desk Officer for EPA, 725 17th Street NW., Washington, DC 20503.

• *Hand/Courier Delivery:* EPA Docket Center, Room 3334, EPA WJC West Building, 1301 Constitution Avenue NW., Washington, DC 20004, Attention Docket ID No. EPA-HQ-OAR-2010-1041 or EPA-HQ-OAR-2010-1042. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments on the Mineral Wool RTR to Docket ID Number EPA-HQ-OAR-2010-1041 and direct your comments on the Wool Fiberglass RTR and proposed area source rule to Docket ID Number EPA-HQ-OAR-2010-1042. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or email. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through <http://www.regulations.gov>, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If the EPA cannot read your comment due to

technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at: <http://www.epa.gov/dockets>.

Docket: The EPA has established dockets for these rulemakings under Docket ID Number EPA-HQ-OAR-2010-1041 (Mineral Wool Production) and EPA-HQ-OAR-2010-1042 (Wool Fiberglass Manufacturing). All documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the EPA Docket Center, EPA/DC, EPA WJC West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Air Docket is (202) 566-1742.

Public Hearing. If anyone contacts the EPA requesting a public hearing by November 18, 2014, the public hearing will be held on November 28, 2014 at the EPA's campus at 109 T.W. Alexander Drive, Research Triangle Park, North Carolina. The hearing will begin at 1:00 p.m. (Eastern Standard Time) and conclude at 5:00 p.m. (Eastern Standard Time). Please contact Ms. Pamela Garrett at (919) 541-7966 or at garrett.pamela@epa.gov to register to speak at the hearing or to inquire as to whether or not a hearing will be held. The last day to pre-register in advance to speak at the hearings will be November 25, 2014. Additionally, requests to speak will be taken the day of the hearings at the hearing registration desk, although preferences on speaking times may not be able to be fulfilled. If you require the service of a translator or special accommodations such as audio description, please pre-register for the hearing, as we may not be able to arrange such accommodations without advance notice. The hearings will provide interested parties the opportunity to present data, views or arguments concerning the proposed action. The EPA will make every effort

to accommodate all speakers who arrive and register. Because these hearings are being held at U.S. government facilities, individuals planning to attend the hearing should be prepared to show valid picture identification to the security staff in order to gain access to the meeting room. Please note that the REAL ID Act, passed by Congress in 2005, established new requirements for entering federal facilities. If your driver's license is issued by Alaska, American Samoa, Arizona, Kentucky, Louisiana, Maine, Massachusetts, Minnesota, Montana, New York, Oklahoma or the state of Washington, you must present an additional form of identification to enter the federal building. Acceptable alternative forms of identification include: Federal employee badges, passports, enhanced driver's licenses and military identification cards. In addition, you will need to obtain a property pass for any personal belongings you bring with you. Upon leaving the building, you will be required to return this property pass to the security desk. No large signs will be allowed in the building, cameras may only be used outside of the building and demonstrations will not be allowed on federal property for security reasons. The EPA may ask clarifying questions during the oral presentations, but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as oral comments and supporting information presented at the public hearing. Commenters should notify Ms. Garrett if they will need specific equipment, or if there are other special needs related to providing comments at the hearings. Verbatim transcripts of the hearings and written statements will be included in the docket for the rulemaking. The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing; however, please plan for the hearings to run either ahead of schedule or behind schedule. Again a hearing will only be held if requested by November 18, 2014. Please contact Ms. Pamela Garrett at 919-541-7966 or at garrett.pamela@epa.gov or visit <http://www.epa.gov/ttn/atw/woolfib/woolfipg.html> to determine if a hearing will be held. If the EPA holds a public hearing, the EPA will keep the record of the hearing open for 30 days after completion of the hearing to provide an opportunity for submission of rebuttal and supplementary information.

FOR FURTHER INFORMATION CONTACT: For questions about these proposed actions,

contact Ms. Susan Fairchild, Sector Policies and Programs Division (D243-04), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-5167; fax number: (919) 541-5450; and email address: fairchild.susan@epa.gov. For information about the applicability of the National Emission Standards for Hazardous Air Pollutants (NESHAP) to a particular entity, contact Scott Throwe, Office of Enforcement and Compliance Assurance, EPA WJC West Building, 1200 Pennsylvania Avenue NW., Mail Code: 2227A, Washington, DC 20460; telephone number: (202) 564-7013; fax number: (202) 564-0050; email address: throwe.scott@epa.gov.

SUPPLEMENTARY INFORMATION:

Preamble Acronyms and Abbreviations. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

AEGL acute exposure guideline levels
BDL below the detection level
CAA Clean Air Act
CBI Confidential Business Information
CFR Code of Federal Regulations
COS Carbonyl sulfide
CRT cathode-ray tubes
DESP dry electrostatic precipitator
EPA Environmental Protection Agency
ESP electrostatic precipitators
FA flame attenuation
GACT generally available control technology
HAP hazardous air pollutants
HCl Hydrogen chloride
HF Hydrogen fluoride
HQ Hazard Quotient
ICR Information Collection Request
lb/ton pounds per ton
lb/year pounds per year
MACT maximum achievable control technology
MIR maximum individual risk
NAICS North American Industry Classification System
NaOH Sodium hydroxide
NESHAP National Emissions Standards for Hazardous Air Pollutants
NPV net present value
NTTAA National Technology Transfer and Advancement Act
OAQPS Office of Air Quality Planning and Standards
OMB Office of Management and Budget
PM Particulate matter
RCRA Resource Conservation and Recovery Act
RDL representative detection level
REL reference exposure level
RFA Regulatory Flexibility Act
RS rotary spin
RTO regenerative thermal oxidizers
RTR residual risk and technology review
SBA Small Business Administration

SSM startup, shutdown, and malfunction
tpy tons per year
TTN Technology Transfer Network
UMRA Unfunded Mandates Reform Act
UPL Upper Prediction Limit
VCS voluntary consensus standards

Organization of this Document. The information in this preamble is organized as follows:

- I. General Information
 - A. Does this action apply to me?
 - B. Where can I get a copy of this document and other related information?
 - C. What should I consider as I prepare my comments for the EPA?
- II. Background
 - A. Summary of the November 25, 2011, Proposal
 - B. Summary of the April 15, 2013, Supplemental Proposal
 - C. What is the purpose of this supplemental proposal?
- III. What are the proposed changes and rationale for these rules?
 - A. What are the proposed changes that affect all rules in this action and what is our rationale?
 - B. What are the proposed changes in this action that affect both the Mineral Wool Production and the Wool Fiberglass Manufacturing RTR rules, and what is our rationale?
 - C. What are the proposed rule amendments that affect only the Mineral Wool Production source category and what is our rationale?
 - D. What are the proposed rule amendments for major sources in the Wool Fiberglass Manufacturing source category and what is our rationale?
 - E. What are the changes to the previously proposed rule requirements for area sources in the Wool Fiberglass Manufacturing source category and what is our rationale?
- IV. Impacts of the Proposed Changes to Mineral Wool Production (Subpart DDD) and Wool Fiberglass Manufacturing (Subparts NNN and NN)
 - A. Subpart DDD—Mineral Wool Production MACT Rule
 - B. Subpart NNN—Wool Fiberglass Manufacturing MACT Rule
 - C. Subpart NN—Wool Fiberglass Manufacturing Area Source (GACT) Rule
- V. Statutory and Executive Order Reviews
 - A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
 - B. Paperwork Reduction Act
 - C. Regulatory Flexibility Act
 - D. Unfunded Mandates Reform Act
 - E. Executive Order 13132: Federalism
 - F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments
 - G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks
 - H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
 - I. National Technology Transfer and Advancement Act

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

I. General Information

A. Does this action apply to me?

Table 1 of this preamble lists the NESHAP and associated regulated industrial source categories that are the subject of this proposal. Table 1 is not

intended to be exhaustive but rather to provide a guide for readers regarding the entities that this proposed action is likely to affect. These proposed standards, once promulgated, will be directly applicable to the affected sources. Federal, state, local and tribal government entities would not be affected by this proposed action. As defined in the “Initial List of Categories of Sources Under Section 112(c)(1) of

the CAA Amendments of 1990” (see 57 FR 31576, July 16, 1992), the Mineral Wool Production source category is any facility engaged in producing mineral wool fiber from slag, rock or other materials, excluding sand or glass. The Wool Fiberglass Manufacturing source category is any facility engaged in the manufacture of wool fiberglass on a rotary spin manufacturing line or on a flame attenuation manufacturing line.

TABLE 1—NESHAP AND INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS PROPOSED ACTION

Source category	NESHAP	NAICS Code ^a
Mineral Wool Production	Mineral Wool Production	327993
Wool Fiberglass Manufacturing	Wool Fiberglass Manufacturing	327993

^a North American Industry Classification System.

B. Where can I get a copy of this document and other related information?

In addition to being available in the dockets, an electronic copy of this action is available on the Internet through the EPA’s Technology Transfer Network (TTN) Web site, a forum for information and technology exchange in various areas of air pollution control. Following signature by the EPA Administrator, the EPA will post a copy of this proposed action at: <http://www.epa.gov/ttn/atw/minwool.minwopg.html> and <http://www.epa.gov/ttn/atw/woolfib.woolfipg.html>. Following publication in the **Federal Register**, the EPA will post the **Federal Register** version of the proposal and key technical documents at this same Web site. Information on the overall residual risk and technology review program is available at the following Web site: <http://www.epa.gov/ttn/atw/rrisk/rtrpg.html>.

C. What should I consider as I prepare my comments for the EPA?

Submitting CBI. Do not submit information containing CBI to the EPA through <http://www.regulations.gov> or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on a disk or CD ROM that you mail to the EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, you must submit a copy of the comment that does not contain the information claimed as CBI for inclusion in the public docket. If you submit a CD ROM or disk that does not

contain CBI, mark the outside of the disk or CD ROM clearly indicating that it does not contain CBI. Information not marked as CBI will be included in the public docket and the EPA’s electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. Send or deliver information identified as CBI only to the following address: Susan Fairchild, c/o OAQPS Document Control Officer (C404–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Docket ID Number EPA–HQ–OAR–2010–1041 (Mineral Wool) or EPA–HQ–OAR–2010–1042 (Wool Fiberglass).

II. Background

A. Summary of the November 25, 2011, Proposal

On November 25, 2011, (76 FR 72770), the EPA proposed revisions to the Mineral Wool Production and the Wool Fiberglass Manufacturing NESHAP, 40 CFR part 63, subparts DDD and NNN, respectively, to address the results of the RTR that the EPA is required to conduct under sections 112(d)(6) and 112(f)(2) (76 FR 72770). In the November 25, 2011, document, we proposed several amendments to both NESHAP and announced our intention to list and regulate area sources in the wool fiberglass area source category pending the collection of new test data.

B. Summary of the April 15, 2013, Supplemental Proposal

On April 15, 2013, (78 FR 22369), the EPA published a supplemental proposal that made corrections to the November 2011 proposal for the Mineral Wool Production and Wool Fiberglass

Manufacturing source categories, addressed certain comments received on the earlier November 25, 2011 proposal, added gas-fired glass-melting furnaces at area sources in the Wool Fiberglass Manufacturing source category to the category list, under CAA sections 112(c)(3) and 112(k)(3)(B), and proposed first time standards for these sources under CAA section 112(d)(5).

C. What is the purpose of this supplemental proposal?

This document also proposes revisions and clarifications to the previous proposals, including, but not limited to:

- Additional explanation of the upper prediction limit (UPL) approach;
- an explanation of our approach to limited datasets;
- an explanation of why we are withdrawing the proposed provisions establishing an affirmative defense to civil penalties for violations caused by malfunctions;
- proposed basis for our determination on ecological effects of pollutants emitted from major sources in these source categories;
- work practice requirements at startup and shutdown for Mineral Wool Production and Wool Fiberglass Manufacturing source categories under CAA section 112(h)(2);
- changes to previously proposed emission limits for the Mineral Wool Production source category;
- changes to previously proposed standards for both major and area sources in the Wool Fiberglass Manufacturing source category.

We are requesting comments on only these aspects of the previously proposed requirements for the Mineral Wool Production RTR, the Wool Fiberglass Manufacturing RTR, and the Wool Fiberglass Manufacturing generally

available control technology (GACT) rule that are presented in this supplemental proposal.

III. What are the proposed changes and rationale for these rules?

A. What are the proposed changes that affect all rules in this action and what is our rationale?

1. Startup, Shutdown, Malfunction

In the 2011 proposal, we proposed to eliminate two provisions that exempt sources from the requirement to comply with the otherwise applicable CAA section 112(d) emission standards during periods of SSM. We also included provisions for affirmative defense to civil penalties for violations of emission standards caused by malfunctions. Periods of startup, normal operations, and shutdown are all predictable and routine aspects of a source's operations. Malfunctions, in contrast, are neither predictable nor routine. Instead they are, by definition sudden, infrequent and not reasonably preventable failures of emissions control, process or monitoring equipment. As explained in the 2011 proposal, the EPA interprets CAA section 112 as not requiring emissions that occur during periods of malfunction to be factored into development of CAA section 112 standards. Under section 112, emissions standards for new sources must be no less stringent than the level "achieved" by the best controlled similar source and for existing sources generally must be no less stringent than the average emission limitation "achieved" by the best performing 12 percent of sources in the category. There is nothing in section 112 that directs the Agency to consider malfunctions in determining the level "achieved" by the best performing sources when setting emission standards. As the D.C. Circuit has recognized, the phrase "average emissions limitation achieved by the best performing 12 percent of" sources "says nothing about how the performance of the best units is to be calculated." *Nat'l Ass'n of Clean Water Agencies v. EPA*, 734 F.3d 1115, 1141 (D.C. Cir. 2013). While the EPA accounts for variability in setting emissions standards, nothing in section 112 requires the Agency to consider malfunctions as part of that analysis. A malfunction should not be treated in the same manner as the type of variation in performance that occurs during routine operations of a source. A malfunction is a failure of the source to perform in a "normal or usual manner" and no statutory language compels the EPA to

consider such events in setting section 112 standards.

Further, accounting for malfunctions in setting emission standards would be difficult, if not impossible, given the myriad different types of malfunctions that can occur across all sources in the category and given the difficulties associated with predicting or accounting for the frequency, degree and duration of various malfunctions that might occur. As such, the performance of units that are malfunctioning is not "reasonably" foreseeable. See, e.g., *Sierra Club v. EPA*, 167 F.3d 658, 662 (D.C. Cir. 1999) ("The EPA typically has wide latitude in determining the extent of data-gathering necessary to solve a problem. We generally defer to an agency's decision to proceed on the basis of imperfect scientific information, rather than to 'invest the resources to conduct the perfect study.'") See also, *Weyerhaeuser v. Costle*, 590 F.2d 1011, 1058 (D.C. Cir. 1978) ("In the nature of things, no general limit, individual permit, or even any upset provision can anticipate all upset situations. After a certain point, the transgression of regulatory limits caused by 'uncontrollable acts of third parties,' such as strikes, sabotage, operator intoxication or insanity, and a variety of other eventualities, must be a matter for the administrative exercise of case-by-case enforcement discretion, not for specification in advance by regulation."). In addition, emissions during a malfunction event can be significantly higher than emissions at any other time of source operation. For example, if an air pollution control device with 99 percent removal goes offline as a result of a malfunction (as might happen if, for example, the bags in a baghouse catch fire) and the emission unit is a steady state type unit that would take days to shut down, the source would go from 99 percent control to zero control until the control device was repaired. The source's emissions during the malfunction would be 100 times higher than during normal operations. As such, the emissions over a 4-day malfunction period would exceed the annual emissions of the source during normal operations. As this example illustrates, accounting for malfunctions could lead to standards that are not reflective of (and significantly less stringent than) levels that are achieved by a well-performing non-malfunctioning source. It is reasonable to interpret section 112 to avoid such a result. The EPA's approach to malfunctions is consistent with section 112 and is a reasonable interpretation of the statute.

In the event that a source fails to comply with the applicable CAA section 112 standards as a result of a malfunction event, the EPA would determine an appropriate response based on, among other things, the good faith efforts of the source to minimize emissions during malfunction periods, including preventative and corrective actions, as well as root cause analyses to ascertain and rectify excess emissions. The EPA would also consider whether the source's failure to comply with the CAA section 112 standard was, in fact, "sudden, infrequent, not reasonably preventable" and was not instead "caused in part by poor maintenance or careless operation." 40 CFR 63.2 (definition of malfunction).

If the EPA determines in a particular case that enforcement action against a source for violation of an emission standard is warranted, the source can raise any and all defenses in that enforcement action and the federal district court will determine what, if any, relief is appropriate. The same is true for citizen enforcement actions. Similarly, the presiding officer in an administrative proceeding can consider any defense raised and determine whether administrative penalties are appropriate.

In summary, the EPA interpretation of the CAA and, in particular, section 112 is reasonable and encourages practices that will avoid malfunctions. Administrative and judicial procedures for addressing exceedances of the standards fully recognize that violations may occur despite good faith efforts to comply and can accommodate those situations.

As noted above, the 2011 proposal included an affirmative defense to civil penalties for violations caused by malfunctions. EPA included the affirmative defense in the 2011 proposal as it had in several prior rules in an effort to create a system that incorporates some flexibility, recognizing that there is a tension, inherent in many types of air regulation, to ensure adequate compliance while simultaneously recognizing that despite the most diligent of efforts, emission standards may be violated under circumstances entirely beyond the control of the source. Although the EPA recognized that its case-by-case enforcement discretion provides sufficient flexibility in these circumstances, it included the affirmative defense in the 2011 proposal and in several prior rules to provide a more formalized approach and more regulatory clarity. See *Weyerhaeuser Co. v. Costle*, 590 F.2d 1011, 1057–58 (D.C.

Cir. 1978) (holding that an informal case-by-case enforcement discretion approach is adequate); but see *Marathon Oil Co. v. EPA*, 564 F.2d 1253, 1272–73 (9th Cir. 1977) (requiring a more formalized approach to consideration of “upsets beyond the control of the permit holder.”). Under the EPA’s regulatory affirmative defense provisions, if a source could demonstrate in a judicial or administrative proceeding that it had met the requirements of the affirmative defense in the regulation, civil penalties would not be assessed. The United States Court of Appeals for the District of Columbia Circuit vacated an affirmative defense in one of the EPA’s Section 112 regulations. *NRDC v. EPA*, 749 F.3d 1055 (D.C. Cir., 2014) (vacating affirmative defense provisions in Section 112 rule establishing emission standards for Portland cement kilns). The court found that the EPA lacked authority to establish an affirmative defense for private civil suits and held that under the CAA, the authority to determine civil penalty amounts in such cases lies exclusively with the courts, not the EPA. Specifically, the Court found: “As the language of the statute makes clear, the courts determine, on a case-by-case basis, whether civil penalties are ‘appropriate.’” See *NRDC* at 1063 *21 (“[U]nder this statute, deciding whether penalties are ‘appropriate’ in a given private civil suit is a job for the courts, not EPA.”).

In light of *NRDC*, the EPA is withdrawing its proposal to include a regulatory affirmative defense provision in this rulemaking and in this proposal has eliminated the provisions related to affirmative defense contained in §§ 63.1180 and 63.1386 (the affirmative defense provisions in the proposed rule published in the **Federal Register** on November 25, 2011 (76 FR 72770)). As explained above, if a source is unable to comply with emissions standards as a result of a malfunction, the EPA may use its case-by-case enforcement discretion to provide flexibility, as appropriate. Further, as the D.C. Circuit recognized, in an EPA or citizen enforcement action, the court has the discretion to consider any defense raised and determine whether penalties are appropriate. Cf. *NRDC v. EPA*, 749 F.3d 1055, 1064 (D.C. Cir. 2014) (arguments that violation were caused by unavoidable technology failure can be made to the courts in future civil cases when the issue arises). The same logic applies to EPA administrative enforcement actions.

2. Work Practice Standards for Periods of Startup and Shutdown

In our April 2013 proposal, we proposed an alternative compliance provision that would allow sources subject to the Mineral Wool Production NESHAP, the Wool Fiberglass Manufacturing NESHAP and the Wool Fiberglass Manufacturing GACT standard to demonstrate compliance with applicable standards during startup and shutdown. (78 FR 22378 and 22388). Specifically, we proposed that sources would keep records showing that emissions were routed to the air pollution control devices and that these control devices were operated at the parameters established during the most recent performance test that showed compliance with the emission limit. For electric cold-top furnaces in the Wool Fiberglass Manufacturing source category, we also proposed limiting raw material content at startup and shutdown to only cullet because using cullet reduces hazardous air pollutant (HAP) emissions, and this particular furnace design does not allow the control device to be operated continuously during startup. For all other glass melting furnaces, we also added a requirement for preheating the empty furnace using only natural gas as a means of demonstrating compliance with the emission limits at startup. (78 FR 22388). However, we did not specifically propose these requirements under CAA section 112(h)(2).

After our April 2013 document, we received and reviewed information from the mineral wool and wool fiberglass industries regarding the work practices used during periods of startup and shutdown.^{1,2} The best performers in the wool fiberglass and mineral wool industries identified a variety of practices used by mineral wool and wool fiberglass manufacturers to minimize emissions during periods of startup and shutdown. We analyzed and characterized their practices according to the expected effectiveness of the industries’ measures and according to the best performers in these industries.

At this time, we are proposing under CAA section 112(h)(2) that mineral wool production and wool fiberglass

manufacturing facilities comply with work practice standards that are used by the best performers during periods of startup and shutdown (as described in Section III.D.6. of this preamble. (Work practice standards for previously unregulated HCl and HF emissions from glass-melting furnaces at major sources.)

The work practice standards for startup and shutdown are also being incorporated into the GACT standards for wool fiberglass manufacturing area sources.

In order to promulgate a work practice standard in lieu of an emission standard, the EPA must demonstrate that measurement of the emissions is not practicable due to technological and economic limitations. In the case of these source categories, emissions are not at steady state during startup and shutdown (a necessary factor for accurate emissions testing), and the varying stack conditions, gas compositions, and flow rates make accurate emission measurements impracticable. In addition, startup period for mineral wool cupolas, typically 2 hours, is too short a time to conduct source testing.

3. Environmental Risk Screening Results

In the November 25, 2011 proposal we stated that we did not believe there was a potential for adverse environmental effects because “all chronic non-cancer HQ values considering actual emissions are less than 1 using human health reference values.” Since that time we conducted an environmental risk screening assessment for both source categories in this rulemaking. Additional information on this analysis is available in the risk assessment document titled “Draft Residual Risk Assessment for the Mineral Wool Production and Wool Fiberglass Manufacturing Source Categories” dated October 2014 and available in the docket.

Of the seven pollutants included in the environmental risk screen, the source categories in this rulemaking emit lead, mercury (elemental and divalent), cadmium, hydrogen fluoride and hydrogen chloride. In the Tier I screening analysis for PB–HAP other than lead (which was evaluated differently, as noted in the reference above), none of the individual modeled concentrations for any facility in the source categories exceed any of the ecological benchmarks (either the LOAEL or NOAEL) for mercury or cadmium. Therefore, we did not conduct a Tier II screening assessment. For lead, we did not estimate any exceedances of the secondary lead NAAQS. For HCL and HF, the average

¹ Letter from Angus E. Crane, NAIMA Executive Vice President General Counsel to Susan Fairchild, U.S. Environmental Protection Agency. August 6, 2014. Regarding *NAIMA’s Responses To EPA’s Questions—Work Practices For Startup and Shutdown of Mineral Wool Cupolas*.

² Letter from Angus E. Crane, NAIMA Executive Vice President General Counsel to Susan Fairchild, U.S. Environmental Protection Agency. August 6, 2014. Regarding *NAIMA’s Responses To EPA’s Questions—Work Practices For Startup and Shutdown of Wool Fiberglass Furnaces*.

modeled concentration around each facility (i.e., the average concentration of all off-site data points in the modeling domain) did not exceed any ecological benchmarks (either the LOAEL or NOAEL). In addition, each individual modeled concentration of hydrogen fluoride and hydrogen chloride (i.e., each off-site data point in the modeling domain) was below the ecological benchmarks for all facilities.

B. What are the proposed changes in this action that affect both the Mineral Wool Production and the Wool Fiberglass Manufacturing RTR rules, and what is our rationale?

1. How does the EPA use the UPL in setting maximum achievable control technology (MACT) standards?

The UPL is the statistical methodology the EPA uses as the primary tool to account for emissions variability when setting emissions standards under CAA section 112. The UPL is used to calculate the average emissions limitation achieved over time by the best performing source or sources.

There are several key points that underlie the EPA's methodology for calculating MACT floor standards through the use of the UPL. First, the floor standards reasonably account for variability in the emissions of the sources used to calculate the standards. This variability occurs due to a number of factors, including operation of control technologies, variation in combustion materials and combustion conditions, variation in operation of the unit itself and variation associated with the emission measurement techniques. Second, because the emissions data available to the EPA are in the form of short-term stack tests and the standards must be complied with at all times, the agency uses the UPL to estimate the average emissions performance of the units used to establish the MACT floor standards at times other than when the stack tests were conducted. Thus, the UPL results in a limit that represents the average emissions limitation achieved by the best performing sources over time, accounting for variability in emissions performance.

In establishing MACT floors, we use the available information to determine the average performance of the best performing sources (for existing source floors) and the average performance of the best-controlled similar source (for new source floors). Each MACT standard is based on data from sources whose emissions are expected to vary over their long term performance. For this reason, and because sources must

comply with the MACT standards at all times, consideration of variability is a key factor in establishing these standards. In order to account for variability that is reflected in the available data that we use to calculate MACT floors, we use the UPL. For more information regarding the general use of the UPL and why it is appropriate for calculating MACT floors, see the memorandum titled, *Use of the Upper Prediction Limit for Calculating MACT Floors* (UPL Memo), which is available in the docket for this action.

Furthermore, with regard to calculation of MACT Floor limits based on limited datasets, we considered additional factors as summarized below and described in more details in the memorandum titled, *Approach for Applying the Upper Prediction Limit to Limited Datasets* (Limited Datasets Memo), which is available in the docket for this action.

2. What is our approach for applying the upper prediction limit to limited datasets?

In previous (November 2011 and April 2013) proposals we first ranked the test data by the arithmetic average of each source's emissions test results and we then performed a UPL calculation for the MACT floor population for new and existing sources, using the average emissions data from the best performing source or sources. We have recently further evaluated the way we apply the UPL where we have limited data sets.

The UPL approach addresses variability of emissions data from the best performing source or sources in setting MACT standards. The UPL also accounts for uncertainty associated with emission values in a dataset, which can be influenced by components such as the number of samples available for developing MACT standards and the number of samples that will be collected to assess compliance with the emission limit. The UPL approach has been used in many environmental science applications.^{3 4 5 6 7 8} As explained in

more detail in the UPL Memo, the EPA used the UPL approach to reasonably estimate the emissions performance of the best performing source or sources to establish MACT floor standards.

With regard to the derivation of MACT limits using limited datasets, the D.C. Circuit Court of Appeals raised questions regarding the application of the UPL to limited datasets in its recent decision in *National Association of Clean Water Agencies v. EPA* (NACWA), which involved challenges to the EPA's MACT standards for sewage sludge incinerators. Since the NACWA decision, we have further evaluated this issue in the Limited Datasets Memo, which is available in the docket for this action. We followed the proposed approach documented in the Limited Datasets Memo for each of the proposed MACT floor calculations that is based on a limited dataset. We seek comments on the approach described in the Limited Dataset Memo and whether there are other approaches we should consider for such datasets. We also seek comments on the application of this approach for the derivation of MACT limits based on limited datasets in this supplemental proposal, which are described in the following section of today's document and in the Limited Dataset Memo.

For further explanation on the approach we used to calculate MACT floors based on limited datasets, including the specific MACT floor calculations for the proposed mineral wool and wool fiberglass emission limits, please see the Limited Datasets Memo and the MACT Floor Memo in the dockets for these rules. We are requesting comment on this proposed approach.

3. How did we apply the approach for limited datasets to limited datasets in the Mineral Wool Production and Wool Fiberglass Manufacturing source categories?

The standards where we had limited datasets are listed in sections III C and D below. For the Mineral Wool Production source category, we have

³ Gibbons, R. D. (1987), *Statistical Prediction Intervals for the Evaluation of Ground-Water Quality*. Groundwater, 25: 455–465 and Hart, Barbara F. and Janet Chaseling, *Optimizing Landfill Ground Water Analytes*—New South Wales, Australia, Groundwater Monitoring & Remediation, 2003, 23, 2.

⁴ Wan, Can; Xu, Zhao; Pinson, Pierre; Dong, Zhao Yang; Wong, Kit Po. *Optimal Prediction Intervals of Wind Power Generation*. 2014. IEEE Transactions on Power Systems, ISSN 0885–8950, 29(3): pp. 1166–1174.

⁵ Khosravi, Abbas; Mazloumi, Ehsan; Nahavandi, Saeid; Creighton, Doug; van Lint, J. W. C. *Prediction Intervals to Account for Uncertainties in Travel Time Prediction*. 2011. IEEE Transactions on

Intelligent Transportation Systems, ISSN 1524–9050, 12(2):537–547.

⁶ Ashkan Zarnani; Petr Musilek; Jana Heckenbergerova. 2014. Clustering numerical weather forecasts to obtain statistical prediction intervals. *Meteorological Applications*, ISSN 1350–4827. 21(3): 605.

⁷ Rayer, Stefan; Smith, Stanley K; Tayman, Jeff. 2009. *Empirical Prediction Intervals for County Population Forecasts*. *Population Research and Policy Review*, 28(6): 773–793.

⁸ Nicholas A Som; Nicolas P Zegre; Lisa M Ganio; Arne E Skaugset. 2012. Corrected prediction intervals for change detection in paired watershed studies. *Hydrological Sciences Journal*, ISSN 0262–6667, 57(1): 134–143.

limited datasets for six pollutants and 11 subcategories. For the wool fiberglass category, we have limited datasets for three pollutants and two subcategories. We evaluated these specific datasets to determine whether it is appropriate to make any modifications to the approach used to calculate MACT floors for each of these datasets. For each dataset, we performed the steps outlined in the Limited Dataset Memo, including: Ensuring that we selected the data distribution that best represents each dataset; ensuring that the correct equation for the distribution was then applied to the data; and comparing individual components of each limited dataset to determine if the standards based on limited datasets reasonably represent the performance of the units included in the dataset. The details of each analysis are described and presented below in the applicable sections for both the Mineral Wool Production source category and for the Wool Fiberglass Manufacturing source category, and in the applicable MACT Floor Memos. We seek comments regarding the specific application of the limited dataset approach used to derive the proposed emissions limits for the pollutants described in the MACT Floor Memos.

C. What are the proposed rule amendments that affect only the Mineral Wool Production source category and what is our rationale?

We are proposing revised emission limits for cupolas and for bonded lines as a result of new representative detection limit (RDL) values, new source test data and our approach for calculating MACT floors based on limited data sets, as introduced in section III.B of this preamble.

1. How are the baseline risks different from the risks presented in previous documents for the RTR?

The updated draft risk assessment for the Mineral Wool Production source category, located in the docket for this rulemaking, contains updated estimates of risk based on actual emissions currently emitted by the industry. The risk estimates for actual emissions were updated to incorporate the following model and model reference library updates:

- AERMOD version 11103 was updated to version 14134.
- HEM version 1.3.0 was updated to version 1.3.1.
- Census input files were updated from the 2000 census to the 2010 census.
- Meteorological input files were updated from 1991 data to 2011 data.

The number of meteorological stations contained in the input files increased from approximately 200 to more than 800.

- The dose response input library was revised to include the latest updates.
- The target organ endpoint input library was revised to include the latest updates.

The revisions listed above did not change our estimate of risk from actual emissions when compared to the risk assessment conducted for the April 15, 2013, supplemental proposal. The risk from mineral wool production is driven by formaldehyde and continues to be well within a level we consider to be acceptable (that is, a maximum individual risk (MIR) less than 100-in-1 million). The MIR for cancer for actual baseline emissions remains 10-in-1 million, with the acute noncancer hazard quotient (HQ) remaining at 20 for the reference exposure level (REL) and at 1 for the AEGL-1. The MIR from mineral wool production emissions under the original MACT standard is estimated to be 30-in-1 million (formaldehyde). The MIR for emissions after implementation of this proposal is estimated to be 10-in-1 million. Therefore, the MIR based on allowable emissions (what sources are permitted to emit) after implementation of the RTR decreases by a factor of 3 from MACT allowable levels.

2. What are the reasons for changing the carbonyl sulfide (COS) emission limits for closed-top cupolas?

The April 15, 2013 proposal contained a revised emissions limit for new and reconstructed closed-top mineral wool cupolas of 0.025 pounds (lb)/ton of melt. However, this proposed emission limit is very close to the test method detection limit of approximately 0.02 lb/ton melt.⁹ The expected measurement imprecision for an emissions value occurring at or near the method detection level is about 40 to 50 percent. This large measure of analytic uncertainty decreases as measured values increase: Pollutant measurement imprecision decreases to a consistent relative 10 to 15 percent for values measured at a level about 3 times the method detection level. See American Society of Mechanical Engineers, *Reference Method Accuracy and Precision (ReMAP): Phase 1, Precision of Manual Stack Emission Measurements*, CRTD Vol. 60, February 2001. Thus, if the value equal to three times the representative method detection level were greater than the calculated floor

emissions limit, we would conclude that the calculated floor emissions limit does not account entirely for measurement variability.

That is the case here with the carbonyl sulfide (COS) limit for new and reconstructed closed-top cupolas. The calculated standard (not accounting for the inherent analytical variability in the measurements) is approximately 0.02 lb/ton melt. In order to account for measurement variability, we multiplied the highest reported minimum detection level for the analytic method by a factor of three which results in a level of 0.061 lb/ton melt. This represents the lowest level that can be reliably measured using this test method, and we therefore believe that it is the lowest level we can set as the MACT limit taking the appropriate measurement variability into account.

3. Changes to previously proposed emission limits for horizontal combined collection and curing bonded lines?

In addition to our updated approach for determining the new source limits based on a limited dataset as discussed in section III. B of this preamble, we are proposing to change the proposed limits for formaldehyde, phenol and methanol emissions from horizontal collection/curing lines from previously proposed limits (November 25, 2011 (76 FR 72770 at 72789), and April 15, 2013 (78 FR 22370 at 22386)) due to new test data we received subsequent to our April 2013 proposal. We have since conducted a thorough review of both the first test, upon which the November 2011 proposed limits were based, and the second test, which supported industry's comments on the level of the standard.

In our review of the new test data, we found that emissions were measured at very different production rates than during the first test. We held discussions during several teleconferences with the company managers, environmental managers and the hired testing contractors to obtain additional information that would explain the widely divergent results from the first and second tests. We questioned the contracting company that conducted the source testing to explain under what situation the process tested using the same test method would yield such widely divergent results (which varied up to an order of magnitude).

Each of the source tests included three test runs measuring pollutant concentrations at a single stack to which emissions from both the collection process and the curing oven are vented. Of the three test runs conducted in the

⁹ Determination of RDL and "3 × RDL" Values for Carbonyl Sulfide.

first test, the samples collected were all sent to a laboratory for analysis. The laboratory reported they received half of what was reportedly sent to them for the first and second runs, and reported receiving 10 times the amount reportedly sent to them for the third run. These errors alone should result in an invalid test. However, we were initially unwilling to abandon the first test if corrections could be made by the laboratory or the field tester to produce valid calculations. We found that environmental managers could not account for the apparent sample and collection errors in the first test.

In our review of the second test, we found that all three runs yielded similar results and that the laboratory reported to have received the same amount of sample that the tester reported was collected for analysis; these were important factors in our quality review of the test data.

For these reasons we concluded that the proper action would be to abandon the first test in its entirety due to the sample collection and reporting errors, and use the second test in its place because those samples were collected and reported correctly. The replacement of the first erroneous test with the second correct test changes the emission limits for the horizontal collection/curing subcategory. The revised emission limits being proposed are summarized in Table 2 of this preamble.

Setting aside the issue of whether the source adhered to proper sampling and analysis methods, we considered whether using data from all six test runs from both the first and second tests would have resulted in a significantly different emission limit, even though the first test was invalid. We found that while the correct action is to accept only the valid emission testing, emission limits using all the test data would not have yielded appreciably different emission limits than the limits we are proposing in today's rule. We are requesting comment on the emission limits for horizontal combined collection and curing lines.

4. What previously proposed emission limits are changing as a result of our updated approach to limited datasets?

As a result of our updated approach to evaluate limited datasets (as discussed in Section III.B of this preamble), we are proposing the following for mineral wool cupolas:

- Hydrogen fluoride (HF) and hydrochloric acid (HCl) emissions limits for two subcategories of new cupolas (those processing slag and those not processing slag),
- HCl emission limits for existing cupolas processing slag, and
- COS emission limits for new and existing open top cupolas.

The MACT floor dataset for each pollutant from cupola subcategory (e.g., open-top, processing slag and not processing slag) includes less than seven test runs from multiple cupolas. For each subcategory of cupola, we also identified the best performing unit based on average emissions performance. After determining the dataset distribution for each pollutant and ensuring that we used the correct equation for each distribution, we calculated the MACT floor emission limit for both existing and new sources.

Also based on our updated approach to limited datasets, we are proposing phenol, formaldehyde and methanol emission limits for three subcategories of new and existing bonded lines. Because one source exists in each of the three subcategories of combined collection and curing lines, existing and new source limits are equal. However, as a result of using our updated approach for limited datasets, the emission limits for phenol, formaldehyde and methanol we are proposing at this time for three subcategories of new and existing bonded lines are lower than those previously proposed. The MACT floor dataset for each pollutant from each new combined collection and curing line subcategory (e.g., vertical, horizontal and drum) includes less than seven test runs from a single line that we identified as the best performing unit based on average emissions

performance. After determining the dataset distribution for each pollutant and ensuring that we used the correct equation for the distribution, we calculated the MACT floor emission limit for both existing and new sources. Table 2 indicates where changes to previously proposed emission limits are being newly proposed.

For each of the limited datasets (for both new and existing source floors), we evaluated the reasonableness of the calculated limit based on two factors. First, we reviewed the range of the test runs for each pollutant and process (i.e., an evaluation of the variance of the data). In general, we found the variance was determined to be acceptable because all measurements were within the expected range. Second, we compared the calculated UPL to the arithmetic average and found that the calculated limit was always within approximately 2.5 times the arithmetic average, a range we find when evaluating larger datasets.

Additionally, for new source emission limits, we compared the UPL equation components for the individual unit with those of the units in the existing source floor to determine if our identification of the best unit was reasonable.

The analyses and evaluations we performed for the proposed emissions limits are discussed in detail in the "MACT Floor Memo for the Mineral Wool Production Source Category" and in the "Limited Datasets Memo for the Mineral Wool Production Source Category," available in the docket for this rule.

5. Proposed Emission Limits for the Mineral Wool Production Source Category

In Table 2 below we present all the emission limits for new and existing major sources in the Mineral Wool Production Source Category as proposed in the 2011 proposal, the 2013 supplemental proposal and in this supplemental proposal. We request comments on the proposed limits that have changed from what we previously proposed.

TABLE 2—EMISSION LIMITS FOR MINERAL WOOL PRODUCTION
[lb pollutant/ton melt]

Process	Subcategory	HAP	2011 Proposal	2013 Proposal	2014 Proposal
Cupolas	Existing Open-top	COS	3.3	6.8	No change.
	New Open top	COS	0.017	4.3	3.2.
	Existing Closed Top	COS	3.3	3.4	No change.
	New Closed Top	COS	0.017	0.025	0.062.
	Existing Processing Slag	HF	0.014	0.16	No change
		HCl	0.0096	0.21	0.44.

TABLE 2—EMISSION LIMITS FOR MINERAL WOOL PRODUCTION—Continued
[lb pollutant/ton melt]

Process	Subcategory	HAP	2011 Proposal	2013 Proposal	2014 Proposal
Bonded Lines	New Processing Slag	HF	0.014	0.16	0.015
		HCl	0.0096	0.21	0.012.
	Existing Not Processing Slag	HF	0.014	0.13	No change
		HCl	0.0096	0.43	No change.
	New Not Processing Slag	HF	0.014	0.13	0.018
		HCl	0.0096	0.43	0.015.
	Vertical (Existing and New)	Formaldehyde	0.46	2.7	2.4
		Phenol	0.52	0.74	0.71
		Methanol	0.63	1.0	0.92.
	Horizontal (Existing and New)	Formaldehyde	0.054	No change	0.63
		Phenol	0.15	No change	0.12
		Methanol	0.022	No change	0.049.
	Drum (Existing and New)	Formaldehyde	0.067	0.18	0.17
		Phenol	0.0023	1.3	0.85
		Methanol	0.00077	0.48	0.28.

D. What are the proposed rule amendments for major sources in the Wool Fiberglass Manufacturing source category and what is our rationale?

We are proposing several changes based on comments we received to our April 15, 2013, proposed rules for glass-melting furnaces and bonded lines. These changes include requirements for annual performance tests, extended compliance deadlines and changes to previously proposed emission limits based on our updated approach for calculating MACT standards where there are limited data sets.

We also are proposing work practice standards for HF and HCl emissions from all furnaces subject to 40 CFR part 63, subpart NNN, under CAA section 112(h)(2). We are seeking comments on only these issues or aspects of requirements that are being presented in this document.

1. How are the baseline risks different from the risks presented in previous documents for the RTR?

The updated draft risk assessment for wool fiberglass manufacturing, located in the docket for this rulemaking, contains updated estimates of risk based on actual emissions currently emitted by the industry. The risk estimates for actual emissions were updated to incorporate the following emissions data, model and model reference library updates:

- Changes were made to the actual emissions data to reflect 2012 facility testing data.
- AERMOD version 11103 was updated to version 14134.
- HEM version 1.3.0 was updated to version 1.3.1.
- Census input files were updated from the 2000 census to the 2010 census.

- Meteorological input files were updated from 1991 data to 2011 data. The number of meteorological stations contained in the input files increased from approximately 200 to more than 800.

- The dose response input library was revised to include the latest updates.
- The target organ endpoint input library was revised to include the latest updates.

The revisions listed above did not change our estimate of risk from actual emissions when compared to the risk assessment conducted for the April 15, 2013 supplemental proposal. The risk from wool fiberglass manufacturing is driven by formaldehyde and hexavalent chromium and continues to be well within a level we consider to be acceptable (that is, a MIR less than 100-in-1 million). The MIR cancer for actual baseline emissions remains 20-in-1 million (formaldehyde), with the acute noncancer HQ remaining at 30 for the REL and at 2 for the AEGL-1 (formaldehyde). The MIR from wool fiberglass manufacturing emissions allowed under the original MACT standard is estimated to be 60-in-1 million (formaldehyde).

2. The Risks After Implementation of the Emission Limits in the Rule as Proposed

After implementation of the emission limits, emissions of formaldehyde and chromium will be reduced. As a result, the MIR from wool fiberglass manufacturing emissions after implementation of this proposal is estimated to be 5-in-1 million, with the acute noncancer HQ at 7 for the REL and at 0.3 for the acute exposure guideline levels (AEGL)-1 (formaldehyde). In addition, the number of individuals exposed to cancer risks

above 10-in-1 million will be reduced from 6,900 for actual emissions to zero for this proposal, and the number of individuals exposed to cancer risks above 1-in-1 million will be reduced from 1.2 million for actual emissions to 21,000 for this proposal.

3. Options and Costs to Achieve Chromium Emission Reductions

Based on information provided by industry, we evaluated eight different approaches to reducing chromium from gas-fired wool fiberglass furnaces. This included seven new options, and a re-evaluation of the costs associated with a sodium hydroxide scrubber control option discussed in the previous proposal. These air pollution control technologies or practices were identified by industry as potential compliance options to meet the standard. These options are as follows:

- Raw material substitution—discontinued use of green glass cullet in the raw material furnace charge; this is also a pollution prevention option;
- Furnace rebuild, when chromium emissions approach the limit, and before the end of the furnace's useful life;
- Installation of high efficiency particulate air (HEPA) filters at the outlet of the dry electrostatic precipitator (DESP);
- Installation of Venturi scrubber technology at the outlet of the DESP;
- Installation of a 3-stage filter at the outlet of the DESP;
- Installation of a 3-stage filter with water cleaning at the outlet of the DESP;
- Installation of a membrane baghouse at the outlet of the DESP;
- Installation of a caustic scrubber at the outlet of the DESP, as previously proposed, but with new cost analyses.

According to the results of our analyses, rebuilding the furnace when chromium emissions approach the limit is the most cost-effective approach, and the remaining cost discussion in this section concerns that control option. Our full analysis of the cost effectiveness of the various chromium emission reduction approaches is available in the technology review memo located in the docket to this proposed rule.

As a result, we are revising our analyses regarding how a wool fiberglass manufacturer would choose to meet the limits of this proposed rule. We are not revising the proposed limits or their applicability to all gas-fired glass-melting furnaces.

Based on information from industry (voluntary information collection request (ICR), CAA section 114 responses, emissions test data), there are currently 16 gas-fired glass-melting furnaces among both major and area sources in this source category, 14 of which were tested for chromium emissions. We estimate that there are six gas-fired furnaces located at four facilities that currently do not meet the

proposed chromium compounds emission limit.

We first proposed that a wool fiberglass facility could choose to rebuild the furnace as a way to comply with the chromium emission limits in November 25, 2011, document, at 76 FR 72804. We stated that “both NaOH scrubbers and a furnace rebuild are considered cost effective when hexavalent chromium levels are high.” At that time, we surmised that a wool fiberglass manufacturer would choose non-chromium refractories with which to rebuild the furnace. In that document, we expected that the highest chromium emitting wool fiberglass furnace emitting 550 lb chromium per year would choose to rebuild the furnace to meet the proposed chromium compounds limit. We since learned from industry that the high chromium refractory is needed to withstand the high internal temperature, reactivity, corrosivity and erosivity of the furnace environment, but that some wool fiberglass furnaces are structurally and/or functionally designed to emit chromium at very low levels. As shown by the test data, 10 of the existing 16 gas-fired glass-melting furnaces meet the

chromium limit without additional control beyond the DESP.

We now estimate the cost impact for impacted furnaces based on the example from industry practice that high-emitting furnaces may be rebuilt (or replaced) earlier than they might have been otherwise. The associated costing of this scenario is referred to as the net present value (NPV) approach which is described in the EPA Air Pollution Control Cost Manual (EPA/452/B-02-001), January 2002.

As part of the data collection effort associated with this rulemaking, we collected source test data¹⁰ on 14 furnaces with information on furnace age, last rebricking or repair dates, current furnace age, and anticipated or planned future furnace replacement. We also obtained repeat testing for three rebuilt gas-fired glass-melting furnaces.

Of the 14 tested furnaces, all 4 furnaces over 12 years old exceeded the proposed chromium limit. Of the 10 furnaces under 12 years old, three exceeded the limit (one only marginally), and seven tested in compliance with (i.e., below) the proposed chromium limit.

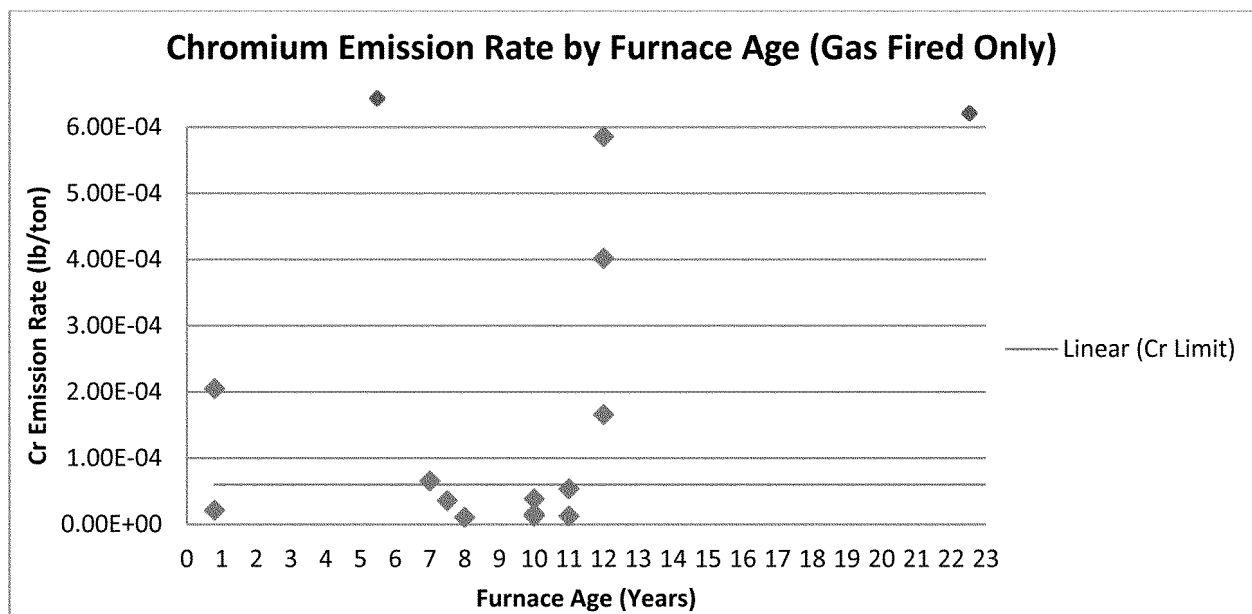


Figure 1. Chromium emissions by furnace age.

We considered two early furnace replacement scenarios based on information we received. In the first, based solely on CAA section 114 responses and test data, the expected

furnace life is 12 years and is reduced to 10 years for compliance with the chromium limit. In the second, based on statements from industry stakeholders, industry press releases and technical

literature, the expected furnace life of 10 years is reduced to 7 years for compliance with the chromium limit.

We decided to use the second (i.e., the 10/7 NPV) scenario as the basis for this industry's NPV approach in an effort to

¹⁰ Of the 16 gas-fired furnaces in this source category, 14 were in operation at the time of testing.

As a result, the EPA obtained source test data only on the 14 operating furnaces.

conservatively show (i.e., more likely to overstate costs than to understate costs) the maximum potential control cost.

Consequently, for this cost analyses, the NPV approach uses the following assumptions: (1) Furnace rebuild cost = \$10 million; (2) normal furnace life cycle = 10 years; (3) chromium compliant furnace life cycle = 7 years; and (4) industry interest rate = 7 percent. As an overview summary, the capital recovery cost is calculated by multiplying the NPV incremental cost

by the capital recovery factor. Using the 7-year furnace life and a 7 percent interest (discount) rate, the annualized capital recovery cost was calculated to be \$212,000 per furnace. A more detailed example calculation of the NPV approach is provided in the Cost Impacts memo located in the docket to this proposed rulemaking.

We found evidence from the industry that several companies chose to rebuild high-chromium emitting furnaces that were more than 6 years old. Data show

that three furnaces initially tested in 2010 were rebuilt and re-tested in 2012 and the results submitted to the EPA. While we do not have a complete set of data showing total chromium emission reductions as a result of all furnace rebuilds, we found that of the available test data for furnaces that were rebuilt, retested and reported, all three achieved chromium emission reductions as a result of the rebuild. In total, chromium emissions were reduced by 47 pounds per year, as shown in Table 3 below.

TABLE 3—REPEATED CHROMIUM TESTING FOR REBUILT FURNACES

Furnace	2010 Emissions rate (lb/ton)	2012 Emission rate (lb/ton)	Comments	2010 Testing emissions (lb/yr)	2012 Testing emissions (lb/yr)
Oxy-Fuel 1	0.000016	0.0000020	Below proposed limit	1.6	0.20
Oxy-Fuel 2	0.00040	0.000021	Below proposed limit	25	1.3
Oxy-Fuel 3	0.00059	0.00021	Neither is below proposed limit	35	12

The results of this new cost analysis were total annualized costs of approximately \$716,000 per year and chromium emissions reductions of 567 lb/year. The cost per lb of emission reduction is approximately \$1,300 per pound. We consider this cost per pound reasonable considering the high toxicity of hexavalent chromium and this cost is consistent with the costs per pound in other recent rulemakings. Because the chromium limit previously proposed under section 112(d)(6) is still cost effective, we are not changing the limit in this proposal. See section V.B for more detailed information on cost impacts.

4. Performance Test Frequency

In our April 2013 proposal, we also proposed reduced testing requirements for sources with emissions that are 75 percent or less of the proposed chromium limit. Specifically, we proposed chromium testing once every three years for sources testing no higher than 75 percent of the proposed chromium limit, i.e., at least 25 percent below the proposed chromium limit (78 FR 22387). Subsequent to our proposal, we conducted an additional review of existing test data and found that source tests show a sudden ramp-up of chromium emissions (at an exponential rate) with furnace age. Therefore, a potential testing period of three years could allow significant emissions of hexavalent chromium to occur before the source realized emissions were increasing. For this reason, we no longer believe that reduced testing frequency is appropriate and, therefore, we are proposing that all gas-fired glass-melting furnaces at both major and area sources

would be required to conduct annual emissions performance testing for chromium compounds using EPA Method 29.

5. Two-Year Compliance Deadline for Gas-Fired Glass-Melting Furnaces at Both Major and Area Sources

We previously proposed (on November 25, 2011, at 76 FR 72793, and on April 15, 2013, at 78 FR 22383–84), a 1-year compliance deadline for affected sources to meet the chromium emission limits of the rule. We received several comments requesting additional time to install new controls that would be effective in removing chromium compounds. In response to these comments, we are proposing up to 2 years from the effective date of this proposed rule for affected sources to comply with the chromium emission limits.

Standards promulgated under CAA section 112(f)(2) shall not apply until 90 days after the effective date of the final action amending this rule and sources may have up to 2 years after the effective date of the standard to comply if the EPA finds that such period is necessary for the installation of controls. (CAA section 112(f)(2)(B).) Under CAA section 112(i)(3), we must require sources to comply as expeditiously as practicable, but no later than 3 years after promulgation of the standard. (*Ass'n of Battery Recyclers v. EPA*, 716 F.3d 667, 405 U.S. App. DC 100, 2013 U.S. App. LEXIS 10637, 76 ERC (BNA) 1609, 43 ELR 20113, 2013 WL 2302713 (D.C. Cir. 2013).

We consulted our records from voluntary ICR responses, CAA section 114 responses regarding furnace ages

and rebuilds, and statements by industry regarding furnace replacements. These sources of information regarding the time period required to replace furnace refractory range from a few weeks (in the case of a “hot repair,” done while the furnace is operating), to 20 months for a complete furnace deconstruction and reconstruction.¹¹

While we no longer believe based on available information that add-on controls would necessarily be used to reduce chromium, we agree that more than 1 year may be needed for sources to decommission the old furnace and install a new furnace (particularly if the new furnace is of a different design than the one it is replacing, and emits chromium at lower rates as it ages).

We also see no reason to allow area sources a longer period of time to install, because we found no difference between furnaces at major and those at area source facilities and companies have demonstrated that “expeditiously as possible” is a period less than 2 years. Further, we are proposing that area and major sources be subject to similar requirements and unnecessary delays reducing the levels of chromium compound emissions to the atmosphere should be avoided for protection of human health. Therefore, we are making no distinction between major and area sources for the chromium compounds emission limit compliance deadline, and instead proposing that affected

¹¹ Three furnaces were rebuilt in the period between the 2010 testing and the 2012 testing. The furnaces were rebuilt according to a different design, and went through shutdown, deconstruction, design, construction, and startup phases during a (slightly less than) 2 year period.

sources comply with the chromium limits within 2 years of the effective date of the final rule.

6. Work Practice Standards for Previously Unregulated HCl and HF Emissions From Glass-Melting Furnaces at Major Sources

In our November 2011 proposal, consistent with the Brick MACT decision, we proposed MACT limits for HF and HCl (at 76 FR 72791) that reflected the average of the best performing 12 percent of existing sources, considering variability. We received comments that these pollutants were emitted at such low levels as to not be measurable and hence may not be emitted by most furnaces. When we reviewed the test data we also found that testing for these HAP indicated levels that were generally well below the detection limit of the test method used. Specifically, over 80 percent of all tests for HCl and 85 percent of all tests for HF were below the detection level of the method. In light of this information, we proposed to require work practice standards for the acid gases HF and HCl from furnaces at major sources in our April 15, 2013, supplemental proposal, under CAA section 112(h)(2). (78 FR 22387.) We did not however, specify the applicable work practice standards at that time.

We note that in response to our April 2013 proposal, wool fiberglass manufacturing owner/operators explained to us that emissions of the acid gases HF and HCl originate from the chloride- and fluoride-bearing constituents of the raw materials used to manufacture fiberglass. Refined raw mineral sands may contain trace amounts of fluorides and chlorides, and certain sources of external glass cullet typically contain significant concentrations of chlorides and fluorides, which undergo chemical transformation in the furnace environment to form the acid gases HCl and HF. These acid gases are undesirable in the wool fiberglass furnace environment because they cause damage to the furnace instruments (thermal sensors, cameras, flow rate sensors, etc.). Due to their location within the continuous high-temperature process, the replacement or repair of furnace components (and problems occurring as a result of compromised furnace components) is very costly. In order to protect furnace components, wool fiberglass facilities identify, isolate and screen out fluoride- and chloride-bearing materials.

According to these facilities, chlorides, fluorides and fluorine are components of glass from industrial

(also known as continuous strand, or textile) fiberglass, cathode ray tubes (CRT), computer monitors that include CRT, glass from microwave ovens and glass from televisions. HF and HCl emissions occur when recycled glass from these types of materials enters the external cullet stream from the recycling center. We have used this information to develop and propose the work practice standard for wool fiberglass manufacturers in this action.

Wool fiberglass facilities ensure their feedstock does not contain chloride-, fluoride-, or fluorine-bearing cullet by one of two approaches. First, the facility may require the providers of external cullet to verify that the cullet does not include waste glass from the chloride-, fluoride- or fluorine-bearing sources mentioned above. Alternatively, facilities may sample their raw materials to show the cullet entering the furnace does not contain glass from these types of sources. The furnace emissions testing shows this is an effective work practice to reduce emissions of these acid gases.

In this document, we are, therefore, proposing work practice standards for the Wool Fiberglass Manufacturing source category that would require wool fiberglass facilities to maintain records from either cullet suppliers or their internal inspections showing that the external cullet is free of components that would form HF or HCl in the furnace exhaust (i.e., chlorides, fluorides and fluorine). Facilities would maintain quality assurance records for raw materials and/or records of glass formulations indicating the facility does not process fluoride-, fluorine-, or chloride-bearing materials in their furnaces, and that they thereby maintain low HF and HCl emissions. Major source facilities would be required to make these records available for inspection by the permitting authority upon demand. Failure to maintain such records would constitute a violation from the requirement.

7. What previously proposed emission limits are changing as a result of our updated approach to limited datasets and what is our rationale?

Only the new source MACT limits are changing as a result of our updated approach to limited datasets. For each of the limited datasets, we evaluated the reasonableness of the calculated limit based on three factors. First, we reviewed the range of the test runs for each pollutant and process (i.e., an evaluation of the variance of the data). In general, we found the variance was determined to be acceptable because all measurements were within the expected

range. Second, we compared the calculated UPL to the arithmetic average, and found that the calculated limit was always within approximately 2.5 times the arithmetic average, a range we find when evaluating larger datasets. Third, we compared the UPL equation components for the individual unit with those of the units in the existing source floor to determine if our identification of the best unit was reasonable.

We are proposing phenol, formaldehyde and methanol emission limits for new sources in both rotary spin (RS) and flame attenuation (FA) subcategories as a result of our updated approach to evaluate limited datasets.

Additionally, we found that one new source limit, the methanol limit for the FA subcategory, was previously proposed equal to the limit for existing sources (0.5 lb/ton of glass pulled). The new source MACT floor dataset for methanol from FA lines includes three test runs from a single line (Johns Manville, Defiance) that we identified as the best performing unit based on average emissions performance.

After determining that the dataset is best represented by a lognormal distribution and ensuring that we used the correct equation for that distribution, we compared the performance of the best controlled similar source to the performance of each of the units in the existing source floor to determine whether our identification of the best controlled similar source was reasonable. Based on our evaluation of the available data, we are now proposing that the MACT floor is 0.35 lb/ton glass pulled for methanol from new FA lines.

For further explanation on the updated approach we are proposing to use for limited datasets, including for the MACT floor calculation for methanol emissions from FA lines please see the "Limited Datasets Memo for the Wool Fiberglass Manufacturing Source Category" and the "MACT Floor Memo for the Wool Fiberglass Manufacturing Source Category" in the dockets for these rules. We are requesting comment on this proposed approach.

8. What are the proposed emission limits for major sources in the Wool Fiberglass Manufacturing Source Category?

Table 4 presents a summary of all the proposed emission limits for new and existing major sources in the Wool Fiberglass Manufacturing source category. We are taking comment only on the changes to previously proposed limits. However, to provide transparency and a complete set of

emission limits for this source category, up to and including this document in
we are including all the limits proposed Table 4 below.

TABLE 4—SUMMARY OF WOOL FIBERGLASS NESHAP EMISSION LIMITS FOR MAJOR SOURCES
[lb/ton glass pulled]

Process	HAP	2011 Proposal	2013 Proposal	2014 Proposal
Existing Rotary Spin Lines	Formaldehyde	0.17	0.19	No change.
	Phenol	0.19	0.26	No change.
	Methanol	0.48	0.83	No change.
New Rotary Spin Lines	Formaldehyde	0.020	0.087	0.066.
	Phenol	0.0011	0.063	0.060.
	Methanol	0.00067	0.61	0.29.
Existing Flame Attenuation Lines	Formaldehyde	5.6	No change	No change.
	Phenol	1.4	No change	No change.
	Methanol	0.50	No change	No change.
New Flame Attenuation Lines	Formaldehyde	3.3	No change	2.6.
	Phenol	0.46	No change	0.44.
	Methanol	0.50	No change	0.35.
Existing and New Furnaces	PM	0.14	0.33	No change
	Chromium Compounds	0.00006	No change	No change

E. What are the changes to the previously proposed rule requirements for area sources in the Wool Fiberglass Manufacturing source category and what is our rationale?

In a change from our April 15, 2013, proposal, we are no longer proposing to establish particulate matter (PM) limits, in addition to the chromium compound limits, for gas-fired glass-melting furnaces at wool fiberglass manufacturing area sources. In the April 15, 2013, document, we proposed both PM and chromium compounds emission limits under CAA section 112(d)(5) (GACT) for wool fiberglass manufacturing gas-fired glass-melting furnaces at area sources. We received comments objecting to the EPA requiring area sources to meet emission limits for both PM and chromium compounds. In one commenter's opinion, separate emission limits for PM and for chromium compounds are inappropriate because PM would no longer be a surrogate for non-mercury HAP metals, and limits for every metal HAP would have to be established. Similarly, another commenter stated that we should set emission limits for either PM or for chromium compounds, but not for both. This commenter further recommended the EPA establish only the PM limit for wool fiberglass manufacturing area sources.

After considering these comments, we are no longer proposing to establish PM limits, in addition to chromium compounds, limits for gas-fired glass-melting furnaces that are located at wool fiberglass manufacturing area sources. As explained in our April 2013 supplemental proposal, chromium compounds are a significant component

of the refractory used above the glass melt line in gas-fired glass-melting furnaces.¹² (78 FR 22373–74). This results in gas-fired glass-melting furnaces emitting particulate that contains chromium in larger amounts than that of electric furnaces. Specifically, PM and chromium emissions test data collected from industry for development of the proposed rule indicates that chromium constitutes an average of 0.96 percent of PM emissions for gas-fired furnaces, which is 13 times higher than the average for electric furnaces (0.07 percent of PM emissions are chromium).¹³ Thus, we believe that because chromium compounds are a significant component of the refractory used above the glass melt line, a greater potential for chromium emissions exists for gas-fired glass-melting furnaces. This is not the case for other HAP metals. The EPA may use a surrogate to regulate HAP if there is reasonable basis to do so and in several rulemakings, we have used PM as a surrogate “for HAP metals because PM control technology traps HAP metal particles and other particulates indiscriminately.” *National Lime v. EPA*, 233 F.3d at 639. But nothing compels the use of a surrogate and EPA must in fact “assure” that there is a “correlation” between PM and non-mercury HAP metal. *Id.*, at 640.

As explained in our April 15, 2013 supplemental proposal, chromium emissions can be still fairly significant

¹² See the 114 responses from all wool fiberglass manufacturers on furnace design, construction, and refractory composition. Also, see product specification statements from St. Gobain, in references.

¹³ See the Modeling File in the Docket for this rule.

after the emission stream passes through any existing PM air pollution control device. Setting emission limits for PM alone would not achieve the objective of the Urban Air Toxics Strategy^{14 15} (Strategy) because chromium compounds is the urban air toxic measured in the emissions from gas-fired glass-melting furnaces.¹⁶ Conversely, setting emission limits for chromium alone achieves the objectives of the Strategy because controls needed to meet the chromium limit will reduce both total PM and its chromium component as the furnace emissions pass through operational PM controls. We also note that for gas-fired glass-melting furnaces, chromium and PM reductions are achieved due to the co-control characteristics of the existing controls (the DESP¹⁷). Because owners/operators must maintain PM controls in order to continue to meet the chromium limits in the rule, PM co-control benefits

¹⁴ The Final Integrated Urban Air Toxics Strategy (Strategy) was published on July 19, 1999 (64 FR 38706).

¹⁵ The Strategy is discussed at length in the April 15, 2013 proposed rule for this source category (78 FR 22370 at 22375–378).

¹⁶ Source testing conducted in October 1995 at a Certainite facility in Mountaintop, PA, shows emissions of PM, including chromium compounds, were emitted from two gas-fired glass-melting furnaces. Emissions of chromium from the outlets of furnaces M1 and M2 were measured at 534 and 964 lb/year, respectively (1,498 lb/year, combined). Both furnaces were ducted to the same DESP. Source testing at the outlet of the DESP measured chromium at 11.4 lb/year. Post-control PM emissions measured 1.63 tons per year.

¹⁷ DESP are the predominant air pollution control devices in place at wool fiberglass gas-fired glass-melting furnaces. Baghouses (fabric filter control) may also be effective. Both of these controls remove PM, a component of which is chromium in the fine particulate form. In our earlier proposals, we had theorized that sources would likely use NaOH scrubbers following the primary PM control.

are realized from the reduction in chromium compounds. We also note that currently, existing PM controls (the DESP with no additional controls) are sufficient to meet the chromium compounds limit at 10 of the existing 16 gas-fired glass-melting furnaces. The chromium compound emission limits for gas-fired glass-melting furnaces at new and existing sources under CAA section 112 (d)(5) are unchanged from the previous proposal. Because it is unchanged, we are not taking comment on the proposed emissions level (note: the previously proposed chromium compounds limit was 6×10^{-5} lb per ton of melt). As previously discussed, we have revised our cost analysis for compliance with the major source chromium limit. We also revised our cost analysis in the same manner for meeting the area source chromium limit. The cost per ton for area sources is \$13,300 per pound. This cost per pound is higher than the cost for major sources, but is still reasonable given the high toxicity of hexavalent chromium and it is comparable to the cost of other recent rulemakings¹⁸ that reduced emissions of hexavalent chromium.

IV. Impacts of the Proposed Changes to Mineral Wool Production (Subpart DDD) and Wool Fiberglass Manufacturing (Subparts NNN and NN)

A. Subpart DDD—Mineral Wool Production MACT Rule

For the proposed amendments to the Mineral Wool Production source category, the air quality, water quality, solid waste and energy impacts were determined based on the need for additional control technologies and actions required to meet the proposed emissions limits. These proposed amendments would maintain emissions of COS, formaldehyde, phenol and methanol emissions at their current low levels.

We do not anticipate any adverse water quality or solid waste impacts from the proposed amendments to the 1999 MACT rule because the proposed requirements would not change the existing requirements that impact water quality or solid waste.

In this supplemental proposal, we have revised the emission limits for horizontal collection and curing activities based on new test data and reevaluated the associated costs. The costs presented below in Table 5 replace those estimated in the April 2013 proposed rule.

As explained in our April 15, 2013, supplemental proposal (78 FR 22370, at 22385), all existing lines that use slag in the raw materials receive the slag from

the iron and steel industry. Some slags contain residual amounts of chlorides and fluorides which vary by process and location.

All existing lines with closed-top cupolas are fitted with RTO which convert the high concentrations of COS in the cupola exhaust gas to energy that is returned to the cupola. This technology reduces the consumption of coke up to 30 percent and, because of the cost of coke, this technology pays for itself over a period of several years. Emissions of COS are below 0.02 lb COS per ton melt when a regenerative thermal oxidizer (RTO) is installed for energy recovery and new source MACT for closed-top cupolas is based upon the use of this technology. Open-top cupolas do not accommodate RTO. This proposed rule establishes a limit of 3.2 lbs COS per ton melt for new lines with open-top cupolas, and 6.8 lbs COS per ton melt for existing lines. All lines currently in operation can meet this limit without new control equipment or different input materials, and thus will not incur additional costs.

The total annualized costs for these proposed amendments are estimated at \$48,800 (2013 dollars) for additional testing and monitoring. Table 6 below provides a summary of the estimated costs and emissions reductions associated with these proposed amendments to the Mineral Wool Production NESHAP.

TABLE 5—ESTIMATED COSTS AND REDUCTIONS FOR THE PROPOSED MINERAL WOOL PRODUCTION MACT STANDARDS (SUBPART DDD) IN THIS ACTION

Proposed amendment	Estimated capital cost (\$MM)	Estimated annual cost (\$MM)	Total HAP emissions reductions (tons per year)	Cost effectiveness in \$ per ton total HAP reduction
Additional testing and monitoring	0	0.049	N/A	N/A

We performed an economic impact analysis for mineral wool consumers and producers nationally, using the annual compliance costs estimated for this proposed rule. The impacts to producers affected by this proposed rule are annualized costs of less than 0.01 percent of their revenues, using the most current year available for revenue data. Prices and output for mineral wool products should increase by no more than the impact on cost to revenues for producers; thus, mineral wool prices should increase by less than 0.01 percent. Hence, the overall economic impact of this proposed rule should be

low on the affected industries and their consumers. For more information, please refer to the Economic Impact and Small Business Analysis for this proposed rulemaking that is in the docket (EPA-HQ-OAR-2010-1042).

B. Subpart NNN—Wool Fiberglass Manufacturing MACT Rule

We evaluated the impacts to the affected sources based on all available information. Two significant sources of information were the 2010 and 2011/2012 emissions testing and subsequent conversations with the North American Insulation Manufacturers Association

and individuals operating industry facilities. According to the 2010 and 2012 emissions test data, there are three glass-melting furnaces at two major source facilities that do not meet the proposed chromium compound emission limit.

Our assessment of impacts is based on the data from tested gas-fired glass-melting furnaces only, and may not be representative of untested furnaces. We anticipate that 10 of the 30 wool fiberglass manufacturing facilities currently operating in the United States are currently major sources and would be affected by these proposed

¹⁸ In the Gold Mines Area Source Rule (76 FR 9450 at 9464) the EPA found that \$13,800 per pound of mercury was cost effective; in the

Chromium Electroplating RTR (77 FR 58220 at 58221), the EPA found that \$14,424 per pound of

chromium at small hard chromium electroplating plants was cost effective.

amendments. We estimate that two of the 10 wool fiberglass manufacturing facilities that are major sources would rebuild three furnaces before the end of their operational lifecycles.

We expect that these proposed RTR amendments would result in reductions of 558 lb of chromium compounds. Hexavalent chromium can be as much as 93 percent (or 547 lb) of the total chromium compounds emitted from wool fiberglass glass-melting furnaces.

Available information indicates that all affected facilities will be able to comply with this proposed work practice standards for HF and HCl without additional controls, and that there will be no measurable reduction in emissions of these gases. Also, we anticipate that there will be no reductions in PM emissions due to these proposed PM standards because all sources currently meet the previously proposed PM limit.

Indirect or secondary air quality impacts include impacts that will result from the increased electricity usage associated with the operation of control devices. We do not anticipate significant

secondary impacts from the proposed amendments to the Wool Fiberglass MACT.

The capital costs for each facility were estimated based on the ability of each facility to meet the proposed emissions limits for PM, chromium compounds, formaldehyde, phenol and methanol. The memorandum, *Cost Impacts of the Proposed NESHAP RTR Amendments for the Wool Fiberglass Manufacturing Source Category*, includes a complete description of the cost estimate methods used for this analysis and is available in the docket.

Under these proposed amendments, eight of the 10 major source wool fiberglass facilities will not incur any capital costs to comply with the proposed emissions limits. Five facilities would be subject to new costs for compliance testing on gas-fired glass-melting furnaces, which will total \$80,000 annually for the entire industry. At this time, there are two facilities with a total of three gas-fired glass-melting furnaces that do not meet the proposed emissions limit for chromium compounds. We anticipate that these

facilities would opt to reduce the operational life cycle for each of the three gas-fired glass-melting furnaces. The estimated capital cost of reducing the operational furnace life from 10 years to 7 years is \$1,144,000 per furnace with a total annualized cost of \$212,000 per furnace. There are a total of eight gas-fired glass-melting furnaces located at five major source facilities. Annual performance testing costs would be \$10,000 per glass-melting furnace, resulting in total glass-melting furnace testing costs of \$80,000.

The 10 major source facilities would incur total annualized costs of \$80,400 for additional compliance testing on their FA and RS manufacturing lines and two of those facilities would incur a total cost of \$1,144,000 for reducing the operational life cycle of three gas-fired glass-melting furnaces due to the proposed rule emission limits. The total annualized costs for the proposed amendments are estimated at \$1.49 million (2013 dollars).

Table 6 below summarizes the costs and emission reductions associated with the proposed amendments.

TABLE 6—ESTIMATED COSTS AND REDUCTIONS FOR THE PROPOSED WOOL FIBERGLASS MANUFACTURING MACT STANDARDS (SUBPART NNN) IN THIS ACTION

Proposed amendment	Est. capital cost (\$mm)	Est. total annualized cost (\$MM)	Total HAP emissions reductions	Cost effectiveness	Number facilities
Gas-Fired Glass-Melting Furnaces: Reduce furnace life cycle	1.144 × 3	0.212 × 3	567 pounds chromium compounds per year.	1,300 (\$ per pound) ..	2
Additional testing and monitoring for gas-fired glass-melting furnaces.	0	0.01 × 8	N/A	5
RS and FA Manufacturing Lines: Operation and Maintenance of thermal oxidizer.	0	0.75	123 tons organic HAP per year.	6,300 (\$ per ton)	6
Additional testing and monitoring for FA and RS lines.	0	0.02	N/A	10

C. Subpart NN—Wool Fiberglass Manufacturing Area Source (GACT) Rule

The impacts presented in this section include the air quality, cost, non-air quality and economic impacts of complying with the proposed GACT rule for wool fiberglass manufacturing located at area source facilities.

We have estimated the potential emission reductions from implementation of the proposed GACT emission standards to be 54 lb of chromium compounds per year.

We considered the costs and benefits of achieving the proposed emission limits and identified five facilities with a total of eight glass-melting furnaces

that would be subject to the proposed requirements. All eight glass-melting furnaces would have to conduct annual testing to demonstrate compliance. Based on the emission testing conducted in 2011 and 2012, three of the eight glass-melting furnaces would need to reduce their emissions to meet the proposed chromium compound emission limits. We estimated that using a reduced life cycle approach for those furnaces would have a capital equipment cost of \$1,144,000 for each furnace and the total annualized costs would be \$212,000 per furnace.

Costs are also incurred for compliance testing, monitoring, recordkeeping, and reporting requirements of the proposed rule. The annual performance testing

costs are \$10,000 per gas-fired glass-melting furnace. Since there are a total of eight gas-fired glass-melting furnaces at the five facilities, the total annual testing cost is \$80,000. The total annualized cost for the wool fiberglass manufacturing industry to comply with subpart NN requirements is \$716,000. The estimated HAP reduction is 50 lb of chromium compounds.

While we do not anticipate the construction of any new wool fiberglass manufacturing facilities in the next 5 years, we do expect most, if not all, of the 10 major source facilities to convert to non-HAP binders and become area sources. However, we did not estimate new source cost impacts for any additional facilities to avoid double

counting the costs associated with the major source rule (subpart NNN) with similar gas-fired glass-melting furnace

requirements. Table 7 below presents the costs to wool fiberglass area sources.

TABLE 7—ESTIMATED COSTS AND REDUCTIONS FOR THE PROPOSED WOOL FIBERGLASS MANUFACTURING AREA SOURCE GACT STANDARDS (SUBPART NN) IN THIS ACTION

Proposed amendment	Est. capital cost (\$MM)	Est. total annualized cost (\$MM)	Total HAP emissions reductions	Cost effectiveness	Number facilities
Reduce furnace life cycle	1.144 × 3	0.212 × 3	54 pounds per year ..	13,300 (\$ per pound)	2
Additional testing and monitoring for glass-melting furnaces.	0	0.01 × 8	N/A	5

The analysis is documented in the memorandum, *Costs and Emission Reductions for the Proposed Wool Fiberglass Manufacturing NESHAP—Area Sources*, and is available in the docket.

We performed an economic impact analysis for wool fiberglass consumers and producers nationally, using the annual compliance costs estimated for this proposed rule. The impacts to producers affected by this proposed rule are annualized costs of less than 0.02 percent of their revenues, using the most current year available for revenue data. Prices and output for wool fiberglass products should increase by no more than the impact on cost to revenues for producers; thus, wool fiberglass prices should increase by less than 0.02 percent. Hence, the overall economic impact of this proposed rule should be low on the affected industries and their consumers. For more information, please refer to the Economic Impact and Small Business Analysis for this proposed rulemaking that is in the docket (EPA-HQ-OAR-2010-1042).

V. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a “significant regulatory action” because it does not raise novel legal or policy issues. Accordingly, the EPA has not submitted this action to OMB for review under Executive Order 12866 and Executive Order 13563 (76 FR 3821, January 21, 2011).

In addition, the EPA prepared an analysis of the potential costs and

benefits associated with this action.

This analysis is contained in *Costs and Emission Reductions for the Proposed Wool Fiberglass Manufacturing NESHAP—Area Source*, in Docket ID No. EPA-HQ-OAR-2010-1042. A copy of the analysis is available in the docket for this action and the analysis is briefly summarized in section IV.C of this preamble.

B. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to OMB under the *Paperwork Reduction Act*, 44 U.S.C. 3501, *et seq.* The ICR document prepared by the EPA has been assigned EPA ICR No. 2481.01.

The information requirements are based on notification, recordkeeping, and reporting requirements in the NESHAP General Provisions (40 CFR part 63, subpart A), which are mandatory for all operators subject to national emission standards. These recordkeeping and reporting requirements are specifically authorized by CAA section 114 (42 U.S.C. 7414). All information submitted to the EPA pursuant to the recordkeeping and reporting requirements for which a claim of confidentiality is made is safeguarded according to agency policies set forth in 40 CFR part 2, subpart B.

This proposed rule would require maintenance inspections of the control devices, and some notifications or reports beyond those required by the General Provisions. The recordkeeping requirements require only the specific information needed to determine compliance. The information collection activities in this ICR include the following: Performance tests, operating parameter monitoring, preparation of a

site-specific monitoring plan, monitoring and inspection, one-time and periodic reports and the maintenance of records. Some information collection activities included in the NESHAP may occur within the first 3 years, and are presented in this burden estimate, but may not occur until 4 or 5 years following promulgation of the proposed standards for some affected sources. To be conservative in our estimate, the burden for these items is included in this ICR. An initial notification is required to notify the Designated Administrator of the applicability of this subpart, and to identify gas-fired glass-melting furnaces subject to this subpart. A notification of performance test must be submitted, and a site-specific test plan written for the performance test, along with a monitoring plan. Following the initial performance test, the source must submit a notification of compliance status that documents the performance test and the values for the operating parameters. A periodic report submitted every 6 months documents the values for the operating parameters and deviations. Owners or operators of mineral wool production and wool fiberglass manufacturing facilities are required to keep records of certain parameters and information for a period of 5 years. We estimate 20 wool fiberglass facilities will be subject to 40 CFR part 63, subpart NN; 10 wool fiberglass facilities are currently subject to 40 CFR part 63, subpart NNN; and 8 mineral wool facilities are currently subject to 40 CFR part 63, subpart DDD. The annual testing, annual monitoring, reporting and recordkeeping burden for this collection (averaged over the first 3 years after the effective date of the standards) is summarized as follows:

Subpart	Labor hours	Labor cost	Non-labor capital cost	Total average annual burden
DDD	123	\$25,850	\$0	\$25,850
NNN	153	46,789	0	46,789

Subpart	Labor hours	Labor cost	Non-labor capital cost	Total average annual burden
NN	77	32,703	0	32,703

These estimates include initial and annual performance tests, conducting and documenting semiannual excess emission reports, maintenance inspections, developing a monitoring plan, notifications and recordkeeping. Monitoring and testing cost were also included in the cost estimates presented in the control costs impacts estimates in section IV of this preamble. The total burden (defined at 5 CFR 1320.3(b)) for the federal government (averaged over the first 3 years after the effective date of the standard) is estimated to be:

Subpart	Federal Gov't labor hours	Federal Gov't labor cost
DDD ...	25	\$1,085
NNN ...	30	1,366
NN	15	695

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

To comment on the agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, the EPA has established public dockets for these rules, which include these ICRs, under Docket ID numbers EPA-HQ-OAR-2010-1042 (subpart DDD) and EPA-HQ-OAR-2010-1042 (subparts NNN and NN). Submit any comments related to the ICRs to the EPA and the OMB. See **ADDRESSES** section at the beginning of this document for where to submit comments to the EPA. Send comments to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, Attention: Desk Office for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after November 13, 2014, a comment to OMB is best assured of having its full effect if OMB receives it by December 15, 2014. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

C. Regulatory Flexibility Act

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice

and comment rulemaking requirements under the Administrative Procedure Act, or any other statute, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations and small governmental jurisdictions.

For purposes of assessing the impacts of this proposed rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA's) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. For this source category, which has the general NAICS code 327993 (i.e., Mineral Wool Production and Wool Fiberglass Manufacturing), the SBA small business size standard is 750 employees according to the SBA small business standards definitions.

After considering the economic impacts of this proposed rule on small entities in the Mineral Wool Production and Wool Fiberglass Manufacturing source categories, I certify that this action will not have a significant economic impact on a substantial number of small entities. Five of the seven mineral wool production parent companies affected in this proposed rule are considered to be small entities per the definition provided in this section. There are no small businesses in the Wool Fiberglass Manufacturing source category. We estimate that this proposed rule will not have a significant economic impact on any of those companies.

While there are some costs imposed on affected small businesses as a result of this rulemaking, the costs associated with this action are less than the costs associated with the limits proposed on November 25, 2011. Specifically, the cost to small entities in the Mineral Wool Production source category due to the changes in COS, HF and HCl are lower as compared to the limits proposed on November 25, 2011, and April 15, 2013. None of the five small mineral wool parent companies are expected to have an annualized compliance cost of greater than one

percent of its revenues. All other affected parent companies are not small businesses according to the SBA small business size standard for the affected NAICS code (NAICS 327993). Therefore, we have determined that the impacts for this proposed rule do not constitute a significant economic impact on a substantial number of small entities.

Although these proposed rules would not have a significant economic impact on a substantial number of small entities, the EPA nonetheless has tried to mitigate the impact that these rules would have on small entities. The actions we are proposing to take to mitigate impacts on small businesses include less frequent compliance testing for the entire mineral wool industry and subcategorizing the Mineral Wool Production source category in developing the proposed COS, HF and HCl emissions limits than originally required in the November 25, 2011, proposal. For more information, please refer to the economic impact and small business analysis that is in the docket. We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

This rule does not contain a federal mandate that may result in expenditures of \$100 million or more for state, local and tribal governments, in the aggregate, or the private sector in any 1 year. The total annualized cost of these rules is estimated to be no more than \$2.3 million (2013\$) in any 1 year. Thus, these rules are not subject to the requirements of sections 202 or 205 of UMRA.

This proposed rule is also not subject to the requirements of section 203 of UMRA, because they contain no regulatory requirements that might significantly or uniquely affect small governments. These rules only impact mineral wool and wool fiberglass manufacturing facilities, and, thus, do not impact small governments uniquely or significantly.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and

responsibilities among the various levels of government, as specified in Executive Order 13132. These proposed rules impose requirements on owners and operators of specified major and area sources, and not on state or local governments. There are no wool fiberglass manufacturing facilities or mineral wool production facilities owned or operated by state or local governments. Thus, Executive Order 13132 does not apply to this action.

In the spirit of Executive Order 13132, and consistent with the EPA policy to promote communications between the EPA and state and local governments, the EPA specifically solicits comment on this proposed action from state and local officials.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). These proposed rules impose requirements on owners and operators of specified area and major sources, and not tribal governments. There are no wool fiberglass manufacturing facilities or mineral wool production facilities owned or operated by Indian tribal governments. Thus, Executive Order 13175 does not apply to this action. The EPA specifically solicits additional comment on this proposed action from tribal officials.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. This action is not subject to Executive Order 13045, because it is based solely on technology performance.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355 (May 22, 2001)), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA), Public Law No. 104–113 12(d) (15 U.S.C. 272 note) directs the

EPA to use voluntary consensus standards (VCS) in its regulatory activities, unless to do so would be inconsistent with applicable law or otherwise impractical. VCS are technical standards (e.g., materials specifications, test methods, sampling procedures and business practices) that are developed or adopted by VCS bodies. The NTTAA directs the EPA to provide Congress, through OMB, explanations when the agency decides not to use available and applicable VCS.

This rulemaking involves technical standards. Therefore, the agency conducted searches for the Wool Fiberglass Manufacturing Area Source NESHAP through the Enhanced National Standards Systems Network (NSSN) Database managed by the American National Standards Institute (ANSI). We also contacted voluntary consensus standards (VCS) organizations and accessed and searched their databases.

Under 40 CFR part 63, subpart NN, searches were conducted for EPA Methods 5 and 29. The search did not identify any other VCS that were potentially applicable for this rule in lieu of EPA reference methods.

We proposed VCS under the NTTAA for Wool Fiberglass Manufacturing (NNN) and for Mineral Wool Production (DDD) in November 2011. Commenters asked to have the option to use other EPA methods to measure their emissions for compliance purposes. These are not VCS and as such are not subject to this requirement.

The EPA welcomes comments on this aspect of the proposed rulemaking, and, specifically, invites the public to identify potentially applicable VCS, and to explain why such standards should be used in this regulation.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies and activities on minority populations and low-income populations in the United States.

The EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects

on minority or low-income populations, because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population.

An analysis of demographic data shows that the average percentage of minorities, percentages of the population below the poverty level and the percentages of the population 17 years old and younger, in close proximity to the sources, are similar to the national averages, with percentage differences of 3, 1.8 and 1.7, respectively, at the 3-mile radius of concern. These differences in the absolute number of percentage points from the national average indicate a 9.4-percent, 14.4-percent and 6.6-percent over-representation of minority populations, populations below the poverty level and the percentages of the population 17 years old and younger, respectively.

In determining the aggregate demographic makeup of the communities near affected sources, the EPA used census data at the block group level to identify demographics of the populations considered to be living near affected sources, such that they have notable exposures to current emissions from these sources. In this approach, the EPA reviewed the distributions of different socio-demographic groups in the locations of the expected emission reductions from this proposed rule. The review identified those census block groups with centroids within a circular distance of a 0.5, 5, and 5 miles of affected sources, and determined the demographic and socio-economic composition (e.g., race, income, education, etc.) of these census block groups. The radius of 3 miles (or approximately 5 kilometers) has been used in other demographic analyses focused on areas around potential sources.^{19 20 21 22} There was only one census block group with its centroids within 0.5 miles of any source affected by the proposed rule. The EPA's

¹⁹ U.S. GAO (Government Accountability Office). *Demographics of People Living Near Waste Facilities*. Washington DC: Government Printing Office; 1995.

²⁰ Mohai P, Saha R. *Reassessing Racial and Socio-economic Disparities in Environmental Justice Research*. Demography. 2006;43(2): 383–399.

²¹ Mennis J. *Using Geographic Information Systems to Create and Analyze Statistical Surfaces of Populations and Risk for Environmental Justice Analysis*. *Social Science Quarterly*, 2002;83(1):281–297.

²² Bullard RD, Mohai P, Wright B, Saha R, et al. *Toxic Waste and Race at Twenty 1987–2007*. United Church of Christ. March, 2007.

demographic analysis has shown that these areas, in aggregate, have similar proportions of American Indians, African-Americans, Hispanics and "Other and Multi-racial" populations to the national average. The analysis also showed that these areas, in aggregate, had similar proportions of families with incomes below the poverty level as the national average, and similar populations of children 17 years of age and younger.²³

The EPA defines Environmental Justice to include meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations and policies. To promote meaningful involvement, the EPA has developed a communication and outreach strategy to ensure that interested communities have access to this proposed rule, are aware of its content, and have an opportunity to comment during the comment period. During the comment period, the EPA will publicize the rulemaking via environmental justice newsletters, Tribal newsletters, environmental justice listservs and the Internet, including the EPA Office of Policy Rulemaking Gateway Web site (<http://yosemite.epa.gov/oepi/RuleGate.nsf/>). The EPA will also conduct targeted outreach to environmental justice communities, as appropriate. Outreach activities may include providing general rulemaking fact sheets (e.g., why is this important for my community) for environmental justice community groups, and conducting conference calls with interested communities. In addition, state and Federal permitting requirements will provide state and local governments, and members of affected communities the opportunity to provide comments on the permit conditions associated with permitting the sources by this proposed rule.

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Wool fiberglass manufacturing.

Dated: October 15, 2014.

Gina McCarthy,
Administrator.

For the reasons stated in the preamble, part 63 of title 40, chapter I,

of the Code of Federal Regulations is proposed to be amended as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. Section 63.14 is amended by revising paragraphs (l)(8) and (9) to read as follows:

§ 63.14 Incorporations by reference.

* * * * *

(l) * * *

(8) SW-846-8260B, Volatile Organic Compounds by Gas Chromatography/Mass Spectrometry (GC/MS), Revision 2, December 1996, in EPA Publication No. SW-846, Test Methods for Evaluating Solid Waste, Physical/Chemical Methods, Third Edition, <http://www.epa.gov/osw/hazard/testmethods/sw846/>, IBR approved for §§ 63.1385, 63.11960, 63.11980, and table 10 to subpart HHHHHHH.

(9) SW-846-8270D, Semivolatile Organic Compounds by Gas Chromatography/Mass Spectrometry (GC/MS), Revision 4, February 2007, in EPA Publication No. SW-846, Test Methods for Evaluating Solid Waste, Physical/Chemical Methods, Third Edition, <http://www.epa.gov/osw/hazard/testmethods/sw846/>, IBR approved for §§ 63.1385, 63.11960, 63.11980, and table 10 to subpart HHHHHHH.

* * * * *

■ 3. Subpart NN of part 63, consisting of §§ 63.880 through 63.899, is added to read as follows:

Subpart NN—National Emission Standards for Hazardous Air Pollutants for Wool Fiberglass Manufacturing at Area Sources

Sec.

- 63.880 Applicability.
- 63.881 Definitions.
- 63.882 Emission standards.
- 63.883 Monitoring requirements.
- 63.884 Performance test requirements.
- 63.885 Test methods and procedures.
- 63.886 Notification, recordkeeping, and reporting requirements.
- 63.887 Compliance dates.
- 63.888 Startups and shutdowns.
- 63.889–63.899 [Reserved]

Table 1 to Subpart NN of Part 63—

Applicability of General Provisions (40 CFR Part 63, Subpart A) to Subpart NN

§ 63.880 Applicability.

(a) Except as provided in paragraphs (b) and (c) of this section, the requirements of this subpart apply to the owner or operator of each wool fiberglass manufacturing facility that is

an area source or is located at a facility that is an area source.

(b) The requirements of this subpart apply to emissions of particulate matter (PM) and chromium compounds, as measured according to the methods and procedures in this subpart, emitted from each new and existing gas-fired glass-melting furnace located at a wool fiberglass manufacturing facility that is an area source.

(c) The provisions of subpart A of this part that apply and those that do not apply to this subpart are specified in Table 1 of this subpart.

(d) Gas-fired glass-melting furnaces that are not subject to subpart NNN of this part are subject to this subpart.

(e) Gas-fired glass-melting furnaces using electricity as a supplemental energy source are subject to this subpart

§ 63.881 Definitions.

Terms used in this subpart are defined in the Clean Air Act, in § 63.2, or in this section as follows:

Bag leak detection system means systems that include, but are not limited to, devices using triboelectric, light scattering, and other effects to monitor relative or absolute particulate matter (PM) emissions.

Gas-fired glass-melting furnace means a unit comprising a refractory vessel in which raw materials are charged, melted at high temperature using natural gas and other fuels, refined, and conditioned to produce molten glass. The unit includes foundations, superstructure and retaining walls, raw material charger systems, heat exchangers, exhaust system, refractory brick work, fuel supply and electrical boosting equipment, integral control systems and instrumentation, and appendages for conditioning and distributing molten glass to forming processes. The forming apparatus, including flow channels, is not considered part of the gas-fired glass-melting furnace. Cold-top electric glass-melting furnaces as defined in subpart NNN of this part are not gas-fired glass-melting furnaces.

Glass pull rate means the mass of molten glass that is produced by a single glass-melting furnace or that is used in the manufacture of wool fiberglass at a single manufacturing line in a specified time period.

Manufacturing line means the manufacturing equipment for the production of wool fiberglass that consists of a forming section where molten glass is fiberized and a fiberglass mat is formed and which may include a curing section where binder resin in the mat is thermally set and a cooling section where the mat is cooled.

²³ The results of the demographic analysis are presented in *Review of Environmental Justice Impacts: Polyvinyl Chloride*, September 2010, a copy of which is available in the docket.

Wool fiberglass means insulation materials composed of glass fibers made from glass produced or melted at the same facility where the manufacturing line is located.

Wool fiberglass manufacturing facility means any facility manufacturing wool fiberglass.

§ 63.882 Emission standards.

(a) *Emission limits.* (1) *Gas-fired glass-melting furnaces.* On and after the date the initial performance test is completed or required to be completed under § 63.7, whichever date is earlier:

(i) For each existing, new, or reconstructed gas-fired glass-melting furnace you must not discharge or cause to be discharged into the atmosphere in excess of 0.00006 lb of chromium (Cr) compounds per ton of glass pulled (60 lb per million tons glass pulled).

(ii) [Reserved]

(2) *Glass-melting furnaces.* On and after the date the initial performance test is completed or required to be completed under § 63.7, whichever date is earlier.

(b) *Operating limits.* On and after the date on which the performance test required to be conducted by §§ 63.7 and 63.1384 is completed, you must operate all affected control equipment and processes according to the following requirements.

(1)(i) You must initiate corrective action within one hour of an alarm from a bag leak detection system and complete corrective actions in a timely manner according to the procedures in the operations, maintenance, and monitoring plan.

(ii) You must implement a Quality Improvement Plan (QIP) consistent with the compliance assurance monitoring provisions of 40 CFR part 64, subpart D when the bag leak detection system alarm is sounded for more than five percent of the total operating time in a 6-month block reporting period.

(2)(i) You must initiate corrective action within one hour when any 3-hour block average of the monitored electrostatic precipitator (ESP) parameter is outside the limit(s) established during the performance test as specified in § 63.884 and complete corrective actions in a timely manner according to the procedures in the operations, maintenance, and monitoring plan.

(ii) You must implement a QIP consistent with the compliance assurance monitoring provisions of 40 CFR part 64 subpart D when the monitored ESP parameter is outside the limit(s) established during the performance test as specified in § 63.884 for more than five percent of the total

operating time in a 6-month block reporting period.

(iii) You must operate the ESP such that the monitored ESP parameter is not outside the limit(s) established during the performance test as specified in § 63.884 for more than 10 percent of the total operating time in a 6-month block reporting period.

(3)(i) You must initiate corrective action within one hour when any 3-hour block average value for the monitored parameter(s) for a gas-fired glass-melting furnace, which uses no add-on controls, is outside the limit(s) established during the performance test as specified in § 63.884 and complete corrective actions in a timely manner according to the procedures in the operations, maintenance, and monitoring plan.

(ii) You must implement a QIP consistent with the compliance assurance monitoring provisions of 40 CFR part 64, subpart D when the monitored parameter(s) is outside the limit(s) established during the performance test as specified in § 63.884 for more than five percent of the total operating time in a 6-month block reporting period.

(iii) You must operate a gas-fired glass-melting furnace, which uses no add-on technology, such that the monitored parameter(s) is not outside the limit(s) established during the performance test as specified in § 63.884 for more than 10 percent of the total operating time in a 6-month block reporting period.

(4)(i) You must initiate corrective action within one hour when the average glass pull rate of any 4-hour block period for gas-fired glass-melting furnaces equipped with continuous glass pull rate monitors, or daily glass pull rate for glass-melting furnaces not so equipped, exceeds the average glass pull rate established during the performance test as specified in § 63.884, by greater than 20 percent and complete corrective actions in a timely manner according to the procedures in the operations, maintenance, and monitoring plan.

(ii) You must implement a QIP consistent with the compliance assurance monitoring provisions of 40 CFR part 64, subpart D when the glass pull rate exceeds, by more than 20 percent, the average glass pull rate established during the performance test as specified in § 63.884 for more than five percent of the total operating time in a 6-month block reporting period.

(iii) You must operate each gas-fired glass-melting furnace such that the glass pull rate does not exceed, by more than 20 percent, the average glass pull rate established during the performance test

as specified in § 63.884 for more than 10 percent of the total operating time in a 6-month block reporting period.

(5)(i) You must initiate corrective action within one hour when the average pH (for a caustic scrubber) or pressure drop (for a venturi scrubber) for any 3-hour block period is outside the limits established during the performance tests as specified in § 63.884 for each wet scrubbing control device and complete corrective actions in a timely manner according to the procedures in the operations, maintenance, and monitoring plan.

(ii) You must implement a QIP consistent with the compliance assurance monitoring provisions of 40 CFR part 64, subpart D when any scrubber parameter is outside the limit(s) established during the performance test as specified in § 63.884 for more than five percent of the total operating time in a 6-month block reporting period.

(iii) You must operate each scrubber such that each monitored parameter is not outside the limit(s) established during the performance test as specified in § 63.884 for more than 10 percent of the total operating time in a 6-month block reporting period.

§ 63.883 Monitoring requirements.

You must meet all applicable monitoring requirements contained in subpart NNN of this part.

§ 63.884 Performance test requirements.

(a) If you are subject to the provisions of this subpart you must conduct a performance test to demonstrate compliance with the applicable emission limits in § 63.882. Compliance is demonstrated when the emission rate of the pollutant is equal to or less than each of the applicable emission limits in § 63.882. You must conduct the performance test according to the procedures in subpart A of this part and in this section.

(b) You must meet all applicable performance test requirements contained in subpart NNN of this part.

§ 63.885 Test methods and procedures.

(a) You must use the following methods to determine compliance with the applicable emission limits:

(1) Method 1 (40 CFR part 60, appendix A-1) for the selection of the sampling port location and number of sampling ports;

(2) Method 2 (40 CFR part 60, appendix A-1) for volumetric flow rate;

(3) Method 3 or 3A (40 CFR part 60, appendix A-2) for O₂ and CO₂ for diluent measurements needed to correct the concentration measurements to a standard basis;

(4) Method 4 (40 CFR part 60, appendix A–4) for moisture content of the stack gas;

(5) Method 29 (40 CFR part 60, appendix A–8) for the concentration of chromium compounds. Each run must consist of a minimum run time of two hours and a minimum sample volume of two dscm.

(6) An alternative method, subject to approval by the Administrator.

(b) Each performance test shall consist of three runs. You must use the average of the three runs in the applicable equation for determining compliance.

§ 63.886 Notification, recordkeeping, and reporting requirements.

You must meet all applicable notification, recordkeeping and reporting requirements contained in subpart NNN of this part.

§ 63.887 Compliance dates.

(a) *Compliance dates.* The owner or operator subject to the provisions of this subpart shall demonstrate compliance with the requirements of this subpart by no later than:

(1) Except as noted in paragraph (a)(3) of this section, the compliance date for an owner or operator of an existing plant or source subject to the provisions in this subpart would be [2 YEARS AFTER EFFECTIVE DATE OF FINAL RULE].

(2) Except as noted in paragraph (a)(3) of this section, the compliance date for

new and reconstructed plants or sources is upon startup of a new gas-fired glass-melting furnace or on [EFFECTIVE DATE OF FINAL RULE].

(3) The compliance date for the provisions related to the electronic reporting provisions of § 63.886 is on [EFFECTIVE DATE OF FINAL RULE].

(b) *Compliance extension.* The owner or operator of an existing source subject to this subpart may request from the Administrator an extension of the compliance date for the emission standards for one additional year if such additional period is necessary for the installation of controls. You must submit a request for an extension according to the procedures in § 63.6(i)(3).

§ 63.888 Startups and shutdowns.

(a) The provisions set forth in this subpart apply at all times.

(b) You must not shut down items of equipment that are required or utilized for compliance with the provisions of this subpart during times when emissions are being routed to such items of equipment, if the shutdown would contravene requirements of this subpart applicable to such items of equipment. This paragraph (b) does not apply if you must shut down the equipment to avoid damage due to a contemporaneous startup or shutdown, of the affected source or a portion thereof.

(c) Startup begins when the wool fiberglass gas-fired glass-melting furnace has any raw materials added. Startup ends when molten glass begins to flow from the glass-melting furnace.

(d) Shutdown begins when the heat sources to the glass-melting furnace are reduced to begin the glass-melting furnace shut down process. Shutdown ends when the glass-melting furnace is empty or the contents are sufficiently viscous to preclude glass flow from the glass-melting furnace.

(e) For a new or existing affected source, to demonstrate compliance with the gas-fired glass-melting furnace emission limits in § 63.882 during periods of startups and shutdowns, demonstrate compliance in accordance with paragraph (f) of this section.

(f) During periods of startups you may demonstrate compliance with the emission limits in § 63.882 by keeping records showing that you used only natural gas or other clean fuels to heat your furnace. During both periods of startups and shutdowns you may demonstrate compliance with the emission limits in § 63.882 by keeping records showing that furnace emissions were controlled using air pollution control devices operated at the parameters established by the most recent performance test that showed compliance with the standard.

§§ 63.889–63.899 [Reserved]

TABLE 1 TO SUBPART NN OF PART 63—APPLICABILITY OF GENERAL PROVISIONS (40 CFR PART 63, SUBPART A) TO SUBPART NN

General provisions citation	Requirement	Applies to subpart NN?	Explanation
§ 63.1	Applicability	Yes	Additional definitions in § 63.881.
§ 63.2	Definitions	Yes	
§ 63.3	Units and Abbreviations	Yes	
§ 63.4	Prohibited Activities	Yes	
§ 63.5	Construction/Reconstruction Applicability.	Yes	
§ 63.5(a)–(c)	Existing, New, Reconstructed	Yes	[Reserved].
§ 63.5(d)	Application for Approval of Construction/Reconstruction.	No	
§ 63.6(e)(1)(i)	No	See § 63.882 for general duty requirements.
§ 63.6(e)(1)(ii)	No	
§ 63.6(e)(1)(iii)	Yes	
§ 63.6(e)(2)	No	
§ 63.6(e)(3)	Startup, Shutdown, and Malfunction Plan.	No	Subpart DDD-no COMS, VE or opacity standards.
§ 63.6(f)(1)	Compliance with Emission Standards.	No	
§ 63.6(g)	Alternative Standard	Yes	
§ 63.6(h)	Compliance with Opacity/VE Standards.	No	
§ 63.6(i)	Extension of Compliance	Yes	§ 63.884 has specific requirements.
§ 63.6(j)	Exemption from Compliance	Yes	
§ 63.7(a)–(d)	Performance Test Requirements Applicability Notification Quality Assurance/Test Plan Testing Facilities.	Yes	
§ 63.7(e)(1)	Conduct of Tests	No	
§ 63.7(e)(2)–(4)	Yes	

TABLE 1 TO SUBPART NN OF PART 63—APPLICABILITY OF GENERAL PROVISIONS (40 CFR PART 63, SUBPART A) TO SUBPART NN—Continued

General provisions citation	Requirement	Applies to subpart NN?	Explanation
§ 63.7(f)–(h)	Alternative Test Method	Yes	See § 63.882(b) for general duty requirement.
	Data Analysis		
	Waiver of Tests		
§ 63.8(a)–(b)	Monitoring Requirements Applica- bility Conduct of Monitoring.	Yes	
§ 63.8(c)(1)(i)	CMS Operation/Maintenance	No	
§ 63.8(c)(1)(ii)	Yes	
§ 63.8(c)(1)(iii)	No	
§ 63.8(c)(2)–(d)(2)	Yes	
§ 63.8(d)(3)	Quality Control	Yes, except for the last sentence.	
§ 63.8(e)–(g)	CMS Performance Evaluation	Yes	
§ 63.9(a)	Notification Requirements Appli- cability.	Yes	Opacity/VE tests not required.
§ 63.9(b)	Initial Notifications	Yes	
§ 63.9(c)	Request for Compliance Exten- sion.	Yes	
§ 63.9(d)	New Source Notification for Spe- cial Compliance Requirements.	Yes	
§ 63.9(e)	Notification of Performance Test ..	Yes	
§ 63.9(f)	Notification of VE/Opacity Test	No	
§ 63.9(g)	Additional CMS Notifications	Yes	
§ 63.9(h)(1)–(3)	Notification of Compliance Status	Yes	
§ 63.9(h)(4)	No	
§ 63.9(i)	Adjustment of Deadlines	Yes	[Reserved]
§ 63.9(j)	Change in Previous Information ...	Yes	
§ 63.10(a)	Recordkeeping/Reporting-Applica- bility.	Yes	
§ 63.10(b)(1)	General Recordkeeping Require- ments.	Yes	
§ 63.10(b)(2)(i)	No	
§ 63.10(b)(2)(ii)	No	
§ 63.10(b)(2)(iii)	Yes	
§ 63.10(b)(2)(iv)–(v)	No	
§ 63.10(b)(2)(vi)–(xiv)	Yes	
§ 63.10(b)(3)	Yes	See § 63.886 for recordkeeping of occurrence and duration of mal- functions and recordkeeping of actions taken during malfunc- tion.
§ 63.10(c)(1)–(9)	Additional CMS Recordkeeping ...	Yes	
§ 63.10(c)(10)–(11)	No	
§ 63.10(c)(12)–(14)	Yes	
§ 63.10(c)(15)	No	
§ 63.10(d)(1)–(4)	General Reporting Requirements Performance Test Results Opacity or VE Observations.	Yes	
§ 63.10(d)(5)	Progress Reports/Startup, Shut- down, and Malfunction Reports.	No	
§ 63.10(e)–(f)	Additional CMS Reports Excess Emission/CMS Performance Reports COMS Data Reports Recordkeeping/Reporting Waiv- er.	Yes	
§ 63.11	Control Device Requirements Ap- plicability Flares.	No	
§ 63.12	State Authority and Delegations ...	Yes	Flares will not be used to comply with the emissions limits.
§ 63.13	Addresses	Yes	
§ 63.14	Incorporation by Reference	Yes	
§ 63.15	Information Availability/Confiden- tiality.	Yes	

Subpart DDD—National Emission Standards for Hazardous Air Pollutants for Mineral Wool Production

■ 4. Section 63.1178 is amended by revising paragraph (a)(2) and adding paragraphs (a)(3) through (5) to read as follows:

§ 63.1178 For cupolas, what standards must I meet?

- (a) * * *
- (2) Limit emissions of carbonyl sulfide (COS) from each existing, new, or reconstructed closed-top cupola to the following:
- (i) 3.4 lb of COS per ton melt or less for existing closed-top cupolas.
- (ii) 0.062 lb of COS per ton melt or less for new or reconstructed closed-top cupolas.
- (3) Limit emissions of COS from each existing, new, or reconstructed open-top cupola to the following:
- (i) 6.8 lb of COS per ton melt or less for existing open-top cupolas.
- (ii) 3.2 lb of COS per ton melt or less for new or reconstructed open-top cupolas.
- (4) Limit emissions of hydrogen fluoride (HF) from each existing, new, or reconstructed cupola to the following:
- (i) 0.16 lb of HF per ton of melt or less for existing cupolas using slag as a raw material.
- (ii) 0.015 lb of HF per ton of melt or less for new or reconstructed cupolas using slag as a raw material.
- (iii) 0.13 lb of HF per ton of melt or less for existing cupolas that do not use slag as a raw material.
- (iv) 0.018 lb of HF per ton of melt or less for new or reconstructed cupolas that do not use slag as a raw material.
- (5) Limit emissions of hydrogen chloride (HCl) from each existing, new, or reconstructed cupola to the following:
- (i) 0.44 lb of HCl per ton of melt or less for existing cupolas using slag as a raw material.
- (ii) 0.012 lb of HCl per ton of melt or less for new or reconstructed cupolas using slag as a raw material.
- (iii) 0.43 lb of HCl per ton of melt or less for existing cupolas that do not use slag as a raw material.
- (iv) 0.015 lb of HCl per ton of melt or less for new or reconstructed cupolas that do not use slag as a raw material.
- * * *

■ 5. Section 63.1179 is amended by revising the section heading and

paragraphs (a) and (b) introductory text to read as follows:

§ 63.1179 For combined collection/curing operations, what standards must I meet?

(a) You must control emissions from each existing and new combined collection/curing operations by limiting emissions of formaldehyde, phenol, and methanol to the following:

- (1) For combined drum collection/curing operations:
- (i) 0.17 lb of formaldehyde per ton melt or less,
- (ii) 0.85 lb of phenol per ton melt or less, and
- (iii) 0.28 lb of methanol per ton melt or less.
- (2) For combined horizontal collection/curing operations:
- (i) 0.63 lb of formaldehyde per ton melt or less,
- (ii) 0.12 lb of phenol per ton melt or less, and
- (iii) 0.049 lb of methanol per ton melt or less.
- (3) For combined vertical collection/curing operations:
- (i) 2.4 lb of formaldehyde per ton melt or less,
- (ii) 0.71 lb of phenol per ton melt or less, and
- (iii) 0.92 lb of methanol per ton melt or less.
- (b) You must meet the following operating limits for each combined collection/curing operations subcategory:
- * * *

■ 6. Section 63.1180 is amended by revising paragraph (d) to read as follows:

§ 63.1180 When must I meet these standards?

(d) At all times, you must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. Determination of whether such operation and maintenance procedures are being used will be based on information available to the Administrator which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source.

■ 7. Section 63.1196 is amended by adding definitions in alphabetical order

for “Closed-top cupola,” “Combined collection/curing operations,” and “Open-top cupola” to read as follows:

§ 63.1196 What definitions should I be aware of?

* * *

Closed-top cupola means a cupola that operates as a closed (process) system and has a restricted air flow rate.

* * *

Combined collection/curing operations means the combination of fiber collection operations and curing ovens used to make bonded products.

* * *

Open-top cupola means a cupola that is open to the outside air and operates with an air flow rate that is unrestricted and at low pressure.

* * *

■ 8. Section 63.1197 is added to read as follows:

§ 63.1197 Startups and shutdowns.

- (a) The provisions set forth in this subpart apply at all times.
- (b) You must not shut down items of equipment that are utilized for compliance with this subpart.
- (c) *Startup* begins when fuels are ignited in the cupola. Startup ends when the cupola produces molten material.

(d) *Shutdown* begins when the cupola has reached the end of the melting campaign and is empty. No mineral wool glass continues to flow from the cupola during shutdown.

(e) During periods of startups and shutdowns you may demonstrate compliance with the emission limits in § 63.1178 according to one of the following methods:

- (1) You may keep records showing that you used only clean fuels during startup and shutdown; or
- (2) You may keep records showing that your emissions were controlled using air pollution control devices operated at the parameters established by the most recent performance test that showed compliance with the standard; or
- (3) You may keep records showing the oxygen level in the cupola exceeds 24 percent.
- 9. Table 1 to subpart DDD of part 63 is revised to read as follows:

TABLE 1 TO SUBPART DDD OF PART 63—APPLICABILITY OF GENERAL PROVISIONS (40 CFR PART 63, SUBPART A) TO SUBPART DDD

General provisions citation	Requirement	Applies to subpart DDD?	Explanation
§ 63.1(a)(1)–(6)	Applicability	Yes	
§ 63.1(a)(7)(9)	No	[Reserved].
§ 63.1(a)(10)–(12)	Yes	
§ 63.1(b)(1)	Initial Applicability Determination ..	Yes	
§ 63.1(b)(2)	No	[Reserved]
§ 63.1(b)(3)	Yes	
§ 63.1(c)(1)–(2)	Yes	
§ 63.1(c)(3)–(4)	No	[Reserved]
§ 63.1(c)(5)–(e)	Yes	
§ 63.2	Definitions	Yes	
§ 63.3	Units and Abbreviations	Yes	
§ 63.4(a)(1)–(2)	Prohibited Activities	Yes	
§ 63.4(a)(3)–(5)	No	[Reserved]
§ 63.4(b)–(c)	Yes	
§ 63.5(a)(1)–(b)(2)	Construction/Reconstruction Ap- plicability.	Yes	
§ 63.5(b)(3)–(4)	Yes	
§ 63.5(b)(5)	No	[Reserved]
§ 63.5(b)(6)	Yes	
§ 63.5(c)	No	[Reserved]
§ 63.5(d)–(j)	Yes	
§ 63.6(a)–(d)	Yes	
§ 63.6(e)(1)(i)	General Duty to minimize emis- sions.	No	See § 63.1180(d) for general duty requirement.
§ 63.6(e)(1)(ii)	Requirement to correct malfunc- tions as soon as possible.	No	§ 63.1187(b) specifies additional requirements.
§ 63.6(e)(1)(iii)	Yes	
§ 63.6(e)(2)	No	[Reserved]
§ 63.6(e)(3)	Startup, Shutdown Malfunction (SSM) Plan.	No	Startups and shutdowns ad- dressed in § 63.1197.
§ 63.6(f)(1)	SSM exemption	No	
§ 63.6(f)(2)–(g)	Yes	
§ 63.6(h)(1)	SSM exemption	No	
§ 63.6(h)(2)–(j)	Yes	
§ 63.7(a)–(d)	Performance testing requirements	Yes	
§ 63.7(e)(1)	Conduct of performance tests	No	See § 63.1180.
§ 63.7(e)(2)–(f)	Yes	
§ 63.7(g)(1)	Data analysis, recordkeeping and reporting.	Yes	
§ 63.7(g)(2)	No	[Reserved]
§ 63.7(g)(3)–(h)	Yes	
§ 63.8(a)–(b)	Monitoring requirements	Yes	
§ 63.8(c)(1)(i)	General duty to minimize emis- sions and CMS operation.	No	See § 63.1180(e) for general duty requirement.
§ 63.8(c)(1)(ii)	Yes	
§ 63.8(c)(1)(iii)	Requirement to develop SSM Plan for CMS.	No	
§ 63.8(c)(2)–(d)(2)	Yes	
§ 63.8(d)(3)	Written procedures for CMS	Yes, except for last sentence, which refers to SSM plan. SSM plans are not required.	
§ 63.8(e)–(g)	Yes	
§ 63.9(b)(1)–(2)	Initial Notifications	Yes	
§ 63.9(b)(3)	No	[Reserved]
§ 63.9(b)(4)–(5)	Yes	
§ 63.9(c)–(j)	Yes	
§ 63.10(a)	Recordkeeping and reporting re- quirements.	Yes	
§ 63.10(b)(1)	General recordkeeping require- ments.	Yes	
§ 63.10(b)(2)(i)	Recordkeeping of occurrence and duration of startups and shut- downs.	No	
§ 63.10(b)(2)(ii)	Recordkeeping of malfunctions	No	See § 63.1193(c) for record- keeping of (ii) occurrence and duration and (iii) actions taken during malfunction.
§ 63.10(b)(2)(iii)	Maintenance records	Yes	
§ 63.10(b)(2)(iv)–(v)	Actions taken to minimize emis- sions during SSM.	No	

TABLE 1 TO SUBPART DDD OF PART 63—APPLICABILITY OF GENERAL PROVISIONS (40 CFR PART 63, SUBPART A) TO SUBPART DDD—Continued

General provisions citation	Requirement	Applies to subpart DDD?	Explanation
§ 63.10(b)(2)(vi)	Recordkeeping for CMS malfunctions.	Yes	
§ 63.10(b)(2)(vii)–(xiv)	Other CMS requirements	Yes	
§ 63.10(b)(3)	Recordkeeping requirement for applicability determinations.	Yes	
§ 63.10(c)(1)–(6)	Additional recordkeeping requirements for sources with CMS.	Yes	
§ 63.10(c)(7)–(8)	Additional recordkeeping requirements for CMS—identifying exceedances and excess emissions.	Yes	
§ 63.10(c)(9)	No	[Reserved] See § 63.1192 for recordkeeping of malfunctions.
§ 63.10(c)(10)–(11)	No	
§ 63.10(c)(12)–(14)	Yes	
§ 63.10(c)(15)	Use of SSM Plan	No	
§ 63.10(d)(1)–(4)	General reporting requirements ...	Yes	
§ 63.10(d)(5)	SSM reports	No	See § 63.1193(f) for reporting of malfunctions.
§ 63.10(e)–(f)	Additional CMS Reports	Yes	
	Excess Emission/CMS Performance Reports.		
	COMS Data Reports		
§ 63.11(a)–(b)	Recordkeeping/Reporting Waiver Control Device Requirements Applicability Flares.	No	Flares will not be used to comply with the emissions limits.
§ 63.11(c)	Alternative Work Practice for Monitoring Equipment for Leaks.	Yes	
§ 63.11(d)	Alternative Work Practice Standard.	Yes	
§ 63.12	State Authority and Delegations ...	No	Flares will not be used to comply with the emissions limits.
§ 63.13	Addresses	Yes	
§ 63.14	Incorporation by Reference	Yes	
§ 63.15	Information Availability/Confidentiality.	Yes	

Subpart NNN—National Emission Standards for Hazardous Air Pollutants for Wool Fiberglass Manufacturing

■ 10. Section 63.1380 is amended by revising paragraph (b)(3) to read as follows:

§ 63.1380 Applicability.

* * * * *

(b) * * *

(3) Each new and existing flame attenuation wool fiberglass manufacturing line producing a bonded product.

* * * * *

■ 11. Section 63.1381 is amended by adding a definition in alphabetical order for “Gas-fired glass-melting furnace” to read as follows:

§ 63.1381 Definitions.

* * * * *

Gas-fired glass-melting furnace means a unit comprising a refractory vessel in which raw materials are charged, melted at high temperature using natural gas and other fuels, refined, and

conditioned to produce molten glass. The unit includes foundations, superstructure and retaining walls, raw material charger systems, heat exchangers, exhaust system, refractory brick work, fuel supply and electrical boosting equipment, integral control systems and instrumentation, and appendages for conditioning and distributing molten glass to forming processes. The forming apparatus, including flow channels, is not considered part of the gas-fired glass-melting furnace. Cold-top electric glass-melting furnaces as defined in this subpart are not gas-fired glass-melting furnaces.

* * * * *

■ 12. Section 63.1382 is amended by revising paragraphs (a)(1) through (3) to read as follows:

§ 63.1382 Emission standards.

(a) * * *

(1) *Glass-melting furnaces.* On and after the date the initial performance test is completed or required to be

completed under § 63.7, whichever date is earlier:

(i) For each existing, new, or reconstructed glass-melting furnace you must not discharge or cause to be discharged into the atmosphere in excess of 0.33 pound (lb) of particulate matter (PM) per ton glass pulled;

(ii) For each existing, new, or reconstructed gas-fired glass-melting furnace you must not discharge or cause to be discharged into the atmosphere in excess of 6.0E–5 lb of chromium (Cr) compounds per ton glass pulled (0.06 lb per thousand tons glass pulled).

(iii) For each existing, new, or reconstructed gas-fired glass-melting furnace you must either:

(A) Require cullet providers to provide records of their inspections showing that the cullet is free of chloride-, fluoride-, and fluorine-bearing constituents; or

(B) Sample your raw materials and maintain records of your sampling showing that the cullet is free of chloride-, fluoride-, and fluorine-bearing constituents.

(2) *Rotary spin manufacturing lines.* On and after the date the initial performance test is completed or required to be completed under § 63.7, whichever date is earlier, the owner or operator shall not discharge or cause to be discharged into the atmosphere in excess of:

(i) For each existing rotary spin (RS) manufacturing line you must not discharge or cause to be discharged into the atmosphere in excess of:

(A) 0.19 lb of formaldehyde per ton glass pulled;

(B) 0.26 lb of phenol per ton glass pulled; and

(C) 0.83 lb of methanol per ton glass pulled.

(ii) For each new or reconstructed RS manufacturing line you must not discharge or cause to be discharged into the atmosphere in excess of:

(A) 0.066 lb of formaldehyde per ton glass pulled;

(B) 0.060 lb of phenol per ton glass pulled; and

(C) 0.29 lb of methanol per ton glass pulled.

(3) *Flame attenuation manufacturing lines.* On and after the date the initial performance test is completed or required to be completed under § 63.7, whichever date is earlier, the owner or operator shall not discharge or cause to be discharged into the atmosphere in excess of:

(i) For each existing flame attenuation (FA) manufacturing line you must not discharge or cause to be discharged into the atmosphere in excess of:

(A) 5.6 lb of formaldehyde per ton glass pulled;

(B) 1.4 lb of phenol per ton glass pulled; and

(C) 0.50 lb of methanol per ton glass pulled.

(ii) For each new or reconstructed FA manufacturing line you must not discharge or cause to be discharged into the atmosphere in excess of:

(A) 2.6 lb of formaldehyde per ton glass pulled;

(B) 0.44 lb of phenol per ton glass pulled; and

(C) 0.35 lb of methanol per ton glass pulled.

* * * * *

■ 13. Section 63.1384 is amended by adding paragraphs (d) and (e) to read as follows:

§ 63.1384 Performance test requirements.

* * * * *

(d) Following the initial performance or compliance test to be conducted within 90 days of the promulgation date of this rule to demonstrate compliance with the chromium compounds emissions limit specified in

§ 63.1382(a)(i), you must conduct an annual performance test for chromium compounds emissions from each glass-melting furnace (no later than 12 calendar months following the previous compliance test).

(e) Following the initial performance or compliance test to demonstrate compliance with the PM, formaldehyde, phenol, and methanol emissions limits specified in § 63.1382, you must conduct a performance test to demonstrate compliance with each of the applicable PM, formaldehyde, phenol, and methanol emissions limits in § 63.1382 at least once every five years.

■ 14. Section 63.1385 is amended by:

■ a. Revising paragraphs (a)(5) and (6);

■ b. Removing the period at the end of paragraph (a)(10) and adding a semicolon in its place; and

■ c. Adding paragraphs (a)(11) through (15) to read as follows:

§ 63.1385 Test methods and procedures.

(a) * * *

(5) Method 5 (40 CFR part 60, appendix A–3) for the concentration of total PM. Each run must consist of a minimum run time of two hours and a minimum sample volume of two dry standard cubic meters (dscm). The probe and filter holder heating system may be set to provide a gas temperature no greater than 120±14°C (248±25°F);

(6) Method 318 (appendix A of this part) for the concentration of formaldehyde, phenol, and methanol. Each test run must consist of a minimum of 10 spectra;

* * * * *

(11) Method 316 (appendix A of this part) for the concentration of formaldehyde. Each test run must consist of a minimum of two hours and two dry standard cubic meters (dscm) of sample volume;

(12) Method SW–846 8260B (§ 63.14(l)(8)) for the concentration of phenol. Each test run must consist of a minimum of three hours;

(13) Method SW–846 8270D (§ 63.14(l)(9)) for the concentration of phenol. Each test run must consist of a minimum of three hours;

(14) Method 308 (appendix A of this part) for the concentration of methanol. Each test run must consist of a minimum of two hours;

(15) Method 29 (40 CFR part 60, appendix A–8) for the concentration of chromium compounds. Each test run must consist of a minimum of three hours and three dscm of sample volume.

■ 15. Section 63.1386 is amended by revising paragraph (c) and adding paragraph (d)(2)(x) to read as follows:

§ 63.1386 Notification, recordkeeping, and reporting requirements.

* * * * *

(c) *Records and reports for a failure to meet a standard.* (1) In the event that an affected unit fails to meet a standard, record the number of failures since the prior notification of compliance status. For each failure record the date, time and duration of each failure.

(2) For each failure to meet a standard record and retain a list of the affected source or equipment, an estimate of the volume of each regulated pollutant emitted over the standard for which the source failed to meet the standard, and a description of the method used to estimate the emissions.

(3) Record actions taken to minimize emissions in accordance with § 63.1382, including corrective actions to restore process and air pollution control and monitoring equipment to its normal or usual manner of operation.

(4) If an affected unit fails to meet a standard, report such events in the notification of compliance status required by § 63.1386(a)(7). Report the number of failures to meet a standard since the prior notification. For each instance, report the date, time and duration of each failure. For each failure the report must include a list of the affected units or equipment, an estimate of the volume of each regulated pollutant emitted over the standard, and a description of the method used to estimate the emissions.

(d) * * *

(2) * * *

(x) You must maintain records of your cullet sampling or records of inspections from cullet providers.

* * * * *

■ 16. Section 63.1387 is amended by revising paragraph (a)(2) to read as follows:

§ 63.1387 Compliance dates.

(a) * * *

(2) The compliance dates for existing plants and sources are:

(i) [DATE 2 YEARS AFTER PUBLICATION OF THE FINAL RULE IN THE **Federal Register**] for gas-fired glass-melting furnaces.

(ii) [Reserved]

* * * * *

■ 17. Section 63.1388 is revised to read as follows:

§ 63.1388 Startups and shutdowns.

(a) The provisions set forth in this subpart apply at all times.

(b) You must not shut down items of equipment that are required or utilized for compliance with the provisions of this subpart during times when emissions are being, or are otherwise

required to be, routed to such items of equipment.

(c) Startup begins when the wool fiberglass glass-melting furnace has any raw materials added and reaches 50 percent of its typical operating temperature. Startup ends when molten glass begins to flow from the wool fiberglass glass-melting furnace.

(d) Shutdown begins when the heat sources to the glass-melting furnace are reduced to begin the glass-melting furnace shut down process. Shutdown

ends when the glass-melting furnace is empty or the contents are sufficiently viscous to preclude glass flow from the glass-melting furnace.

(e) During periods of startups you may demonstrate compliance with the emission limits in § 63.1382:

(1) by keeping records showing that you used only natural gas or other clean fuels to heat your furnace; or

(2) by keeping records showing that you used only cullet as a raw material in your cold-top furnace.

(f) During both periods of startups and shutdowns you may demonstrate compliance with the emission limits in § 63.1382 by keeping records showing that furnace emissions were controlled using air pollution control devices operated at the parameters established by the most recent performance test that showed compliance with the standard.

■ 18. Table 1 to subpart NNN of part 63 is revised to read as follows:

TABLE 1 TO SUBPART NNN OF PART 63—APPLICABILITY OF GENERAL PROVISIONS (40 CFR PART 63, SUBPART A) TO SUBPART NNN

General provisions citation	Requirement	Applies to subpart NNN?	Explanation
§ 63.1(a)(1)–(5)	Applicability	Yes	[Reserved].
§ 63.1(a)(6)		Yes	
§ 63.1(a)(7)–(9)		No	
§ 63.1(a)(10)–(12)		Yes	
§ 63.1(b)(1)	Initial Applicability Determination	Yes	[Reserved].
§ 63.1(b)(2)		No	
§ 63.1(b)(3)		Yes	
§ 63.1(c)(1)–(2)		Yes	
§ 63.1(c)(3)–(4)		No	[Reserved].
§ 63.1(c)(5)–(e)		Yes	
§ 63.2	Definitions	Yes	
§ 63.3	Units and Abbreviations	Yes	
§ 63.4(a)(1)–(2)	Prohibited Activities	Yes	[Reserved].
§ 63.4(a)(3)–(5)		No	
§ 63.4(b)–(c)		Yes	
§ 63.5(a)–(b)(2)	Construction/Reconstruction Applicability.	Yes	
§ 63.5(b)(3)–(4)		Yes	[Reserved].
§ 63.5(b)(5)		No	
§ 63.5(b)(6)		Yes	
§ 63.6(a)–(d)	Compliance with Standards and Maintenance Requirements.	Yes	
§ 63.6(e)(1)(i)	General Duty to minimize emissions.	No	See § 63.1382(b) for general duty requirement. § 63.1382(b) specifies additional requirements.
§ 63.6(e)(1)(ii)	Requirement to correct malfunctions as soon as possible.	No	
§ 63.6(e)(1)(iii)		Yes	
§ 63.6(e)(2)		No	
§ 63.6(e)(3)	Startup, Shutdown Malfunction Plan.	No	Startups and shutdowns addressed in § 63.1388.
§ 63.6(f)(1)	SSM exemption	No	
§ 63.6(f)(2)–(3)	Methods for Determining Compliance.	Yes	
§ 63.6(g)	Use of an Alternative Nonopacity Emission Standard.	Yes	
§ 63.6(h)(1)	SSM exemption	No	See § 63.1382(b).
§ 63.6(h)(2)–(j)		Yes	
§ 63.7(a)–(d)		Yes	
§ 63.7(e)(1)	Performance testing	No	
§ 63.7(f)	Alternate test method	Yes	[Reserved].
§ 63.7(g)(1)	Data Analysis	Yes	
§ 63.7(g)(2)		No	
§ 63.7(g)(3)		Yes	
§ 63.7(h)	Waiver of performance tests	Yes	See § 63.1382(c) for general duty requirement.
§ 63.8(a)–(b)	Monitoring requirements	Yes	
§ 63.8(c)(1)(i)	General duty to minimize emissions and CMS operation.	No	
§ 63.8(c)(1)(ii)		Yes	
§ 63.8(c)(1)(iii)	Requirement to develop SSM Plan for CMS.	No	Yes, except for last sentence, which refers to SSM plan. SSM plans are not required..
§ 63.8(d)(1)–(2)	Quality control program	Yes	
§ 63.8(d)(3)	Written procedures for CMS	Yes, except for last sentence, which refers to SSM plan. SSM plans are not required..	
§ 63.8(e)–(g)		Yes	
§ 63.9(a)	Notification requirements	Yes	

TABLE 1 TO SUBPART NNN OF PART 63—APPLICABILITY OF GENERAL PROVISIONS (40 CFR PART 63, SUBPART A) TO SUBPART NNN—Continued

General provisions citation	Requirement	Applies to subpart NNN?	Explanation
§ 63.9(b)(1)–(2)	Initial Notifications	Yes	[Reserved].
§ 63.9(b)(3)	No	
§ 63.9(b)(4)–(j)	Yes	
§ 63.10(a)	Recordkeeping and reporting requirements.	Yes	
§ 63.10(b)(1)	General Recordkeeping Requirements.	Yes	See § 63.1386(c)(1) through (3) for recordkeeping of occurrence and duration and actions taken during a failure to meet a standard.
§ 63.10(b)(2)(i)	Recordkeeping of occurrence and duration of startups and shutdowns.	No	
§ 63.10(b)(2)(ii)	Recordkeeping of malfunctions	No	
§ 63.10(b)(2)(iii)	Maintenance records	Yes	
§ 63.10(b)(2)(iv)–(v)	Actions taken to minimize emissions during SSM.	No	
§ 63.10(b)(2)(vi)	Recordkeeping for CMS malfunctions.	Yes	
§ 63.10(b)(2)(vii)–(xiv)	Other CMS requirements	Yes	
§ 63.10(b)(3)	Recordkeeping requirement for applicability determinations.	Yes	
§ 63.10(c)(1)–(6)	Additional recordkeeping requirements for sources with CMS.	Yes	
§ 63.10(c)(7)–(8)	Additional recordkeeping requirements for CMS—identifying exceedances and excess emissions.	Yes	
§ 63.10(c)(9)	No	
§ 63.10(c)(10)–(11)	No	
§ 63.10(c)(12)–(14)	Yes	
§ 63.10(c)(15)	Use of SSM Plan	No	
§ 63.10(d)(1)–(4)	General reporting requirements ...	Yes	See § 63.1386(c)(iii) for reporting of malfunctions.
§ 63.10(d)(5)	SSM reports	No	
§ 63.10(e)–(f)	Additional CMS Reports Excess Emission/CMS Performance Reports COMS Data Reports Recordkeeping/Reporting Waiver.	Yes	Flares will not be used to comply with the emissions limits.
§ 63.11(a)–(b)	Control Device Requirements Applicability Flares.	No	
§ 63.11(c)	Alternative Work Practice for Monitoring Equipment for Leaks.	Yes	
§ 63.11(d)	Alternative Work Practice Standard.	Yes	
§ 63.12	State Authority and Delegations ...	Yes	
§ 63.13	Addresses	Yes	
§ 63.14	Incorporation by Reference	Yes	
§ 63.15	Information Availability/Confidentiality.	Yes	



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Part IV

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50 CFR Part 226

Endangered and Threatened Species; Designation of Critical Habitat for the Puget Sound/Georgia Basin Distinct Population Segments of Yelloweye Rockfish, Canary Rockfish and Bocaccio; Final Rule

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 226

[Docket No. 130404330-4883-02]

RIN 0648-BC76

Endangered and Threatened Species; Designation of Critical Habitat for the Puget Sound/Georgia Basin Distinct Population Segments of Yelloweye Rockfish, Canary Rockfish and Bocaccio

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: We, the National Marine Fisheries Service (NMFS), issue a final rule to designate critical habitat for three species of rockfish listed under the Endangered Species Act (ESA): the threatened yelloweye rockfish (*Sebastes ruberrimus*) Distinct Population Segment (DPS), the threatened canary rockfish (*S. pinniger*) DPS, and the endangered bocaccio (*S. paucispinus*) DPS (listed rockfish) pursuant to section 4 of the ESA. The specific areas in the final designation include 590.4 square miles (1529 square km) of nearshore habitat for canary rockfish and bocaccio, and 414.1 square miles (1072.5 square km) of deepwater habitat for yelloweye rockfish, canary rockfish and bocaccio. This final designation represents a reduction of approximately 15.2 percent (180.3 sq mi, 467 sq km) for canary rockfish and bocaccio, and a reduction of approximately 28 percent (160 sq mi, 416.2 sq km) for yelloweye rockfish, compared to our proposed critical habitat rule on August 6, 2013 (78 FR 47635). We exclude some particular areas from designation because the benefits of exclusion outweigh the benefits of inclusion and exclusion of those areas will not result in the extinction of the species. No areas were excluded based on economic impacts.

This final rule responds to and incorporates public comments received on the proposed rule and supporting documents, as well as peer reviewer comments received on our draft biological report.

DATES: This final rule will take effect on February 11, 2015.

ADDRESSES: Reference materials regarding this rulemaking can be obtained via the Internet at: <http://www.wcr.noaa.gov> or by submitting a request to the Protected Resources

Division, West Coast Region, National Marine Fisheries Service, 7600 Sand Point Way NE., Seattle, WA 98115.

FOR FURTHER INFORMATION CONTACT: Dan Tonnes, NMFS, West Coast Region, Protected Resources Division, at the address above or at 206-526-4643; or Dwayne Meadows, NMFS, Office of Protected Resources, Silver Spring, MD, 301-427-8403.

SUPPLEMENTARY INFORMATION:**Background**

On April 28, 2010, we listed the Puget Sound/Georgia Basin Distinct Population Segments (DPSs) of yelloweye rockfish and canary rockfish as threatened under the Endangered Species Act (ESA), and bocaccio as endangered (75 FR 22276, updated 79 FR 20802, April 14, 2014). A proposed critical habitat rule for the listed DPSs of rockfish was published in the **Federal Register** on August 6, 2013 (78 FR 47635). This rule describes the final critical habitat designation, including responses to public comments and peer reviewer comments, and supporting information on yelloweye rockfish, canary rockfish and bocaccio including biology, distribution and habitat use, and the methods used to develop the final designation.

We considered various alternatives to the critical habitat designation for yelloweye rockfish, canary rockfish, and bocaccio of the Puget Sound/Georgia Basin. The alternative of not designating critical habitat for each species would impose no economic, national security, or other relevant impacts, but would not provide any conservation benefit to the species. This alternative was considered and rejected because it does not meet the legal requirements of the ESA and would not provide for the conservation of each species. The alternative of designating all potential critical habitat areas (i.e., no areas excluded) also was considered and rejected because for some areas the benefits of exclusion outweighed the benefits of inclusion. An alternative to designating all potential critical habitat areas is the designation of critical habitat within a subset of these areas. Under section 4(b)(2) of the ESA, we must consider the economic impacts, impacts on national security, and other relevant impacts of designating any particular area as critical habitat. The Secretary of Commerce (Secretary) has the discretion to exclude an area from designation as critical habitat if the benefits of exclusion (i.e., the impacts that would be avoided if an area were excluded from the designation) outweigh the benefits of designation (i.e., the

conservation benefits to these species if an area were designated), so long as exclusion of the area will not result in extinction of the species. We prepared an analysis describing our exercise of discretion, which is contained in our final Section 4(b)(2) Report (NMFS, 2014c). Under this alternative we are excluding Indian lands as well as several areas under the control of the Department of Defense (DOD). We selected, and are implementing, this alternative because the benefits of excluding these areas outweigh the benefits of including these areas and result in a critical habitat designation that provides for the conservation of listed rockfish while avoiding impacts to Indian lands and impacts to national security. This alternative also meets the requirements under the ESA and our joint NMFS-U.S. Fish and Wildlife Service (USFWS) regulations concerning critical habitat. We estimated a total annualized incremental administrative cost of approximately \$123,000 (discounted at 7 percent) for designating the five specific areas as listed rockfish critical habitat.

Statutory and Regulatory Background for Critical Habitat Designations

The ESA defines critical habitat under section 3(5)(A) as: “(i) The specific areas within the geographical area occupied by the species, at the time it is listed . . . , on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protection; and (ii) specific areas outside the geographical area occupied by the species at the time it is listed . . . upon a determination by the Secretary [of Commerce] that such areas are essential for the conservation of the species.”

Section 4(a) of the ESA precludes military land from designation, where that land is covered by an Integrated Natural Resource Management Plan that the Secretary has found in writing will benefit the listed species.

Section 4(b)(2) of the ESA requires us to designate critical habitat for threatened and endangered species “on the basis of the best scientific data available and after taking into consideration the economic impact, the impact on national security, and any other relevant impact, of specifying any particular area as critical habitat.” It grants the Secretary discretion to exclude any area from critical habitat if she determines “the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat.” The decision to

exclude is wholly discretionary with the Secretary. In adopting this provision, Congress explained that, “[t]he consideration and weight given to any particular impact is completely within the Secretary’s discretion.” H.R. No. 95–1625, at 16–17 (1978; M–37016, “The Secretary’s Authority to Exclude Areas from a Critical Habitat Designation under Section 4(b)(2) of the Endangered Species Act” (Oct. 3, 2008) (DOI 2008, 78 FR 53058, August 18, 2013). The Secretary’s discretion to exclude is limited, as he may not exclude areas that “will result in the extinction of the species.”

Once critical habitat is designated, section 7 of the ESA requires Federal agencies to ensure they do not fund, authorize, or carry out any actions that are likely to destroy or adversely modify that habitat. This requirement is in addition to the section 7 requirement that Federal agencies ensure their actions are not likely to jeopardize the continued existence of listed species.

Yelloweye Rockfish, Canary Rockfish, and Bocaccio Natural History and Habitat Use

Our final Biological Report (NMFS, 2014a) describes the life histories of yelloweye rockfish, canary rockfish and bocaccio in detail, which are summarized here. The U.S. portion of the Puget Sound/Georgia Basin that is occupied by yelloweye rockfish, canary rockfish, and bocaccio can be divided into five areas, or Basins, based on the distribution of each species, geographic conditions, and habitat features. These five interconnected Basins are: (1) The San Juan/Strait of Juan de Fuca Basin, (2) Main Basin, (3) Whidbey Basin, (4) South Puget Sound, and (5) Hood Canal. We describe habitat usage in these Basins where we have available information, in addition to available information about life history and habitat usage outside of these areas. The life histories of listed rockfish include pelagic larval and juvenile stages, followed by a juvenile stage in shallower waters, and a sub-adult/adult stage. Much of the life history of these three species is similar, with differences noted below.

Rockfishes are iteroparous (i.e., have multiple reproductive cycles during their lifetime) and are typically long-lived (Love *et al.*, 2002). Yelloweye rockfish are one of the longest lived of the rockfishes, reaching more than 100 years of age. Yelloweye rockfish reach 50 percent maturity at sizes of 16 to 20 in (40 to 50 cm) and ages of 15 to 20 years (Rosenthal *et al.*, 1982; Yamanaka and Kronlund, 1997). The maximum age of canary rockfish is at least 84 years

(Love *et al.*, 2002), although 60 to 75 years is more common (Cailliet *et al.*, 2000). Canary rockfish reach 50 percent maturity at sizes around 16 in (40 centimeters) and ages of 7 to 9 years. The maximum age of bocaccio is unknown, but may exceed 50 years. Bocaccio are reproductively mature near age 6 (FishBase, 2010). Mature females of each species produce from several thousand to over a million eggs annually (Love *et al.*, 2002). Being long-lived allows each species to persist through many years of poor reproduction until a good recruitment year occurs.

Rockfishes fertilize their eggs internally and the young are extruded as larvae. Upon parturition (birth), larval rockfishes can occupy the full water column, but generally occur in the upper 80 m (262 ft) (Love *et al.*, 2002; Weis, 2004). Larval rockfishes have been documented in Puget Sound (Greene and Godersky, 2012), yet most studies have not identified individual fish to species. There is little information regarding the habitat requirements of rockfish larvae, though other marine fish larvae biologically similar to rockfish larvae are vulnerable to low dissolved oxygen levels and elevated suspended sediment levels that can alter feeding rates and cause abrasion to gills (Boehlert, 1984; Boehlert and Morgan, 1985; Morgan and Levings, 1989). Larvae have also been observed immediately under free-floating algae, seagrass, and detached kelp (Shaffer *et al.*, 1995; Love *et al.*, 2002). Oceanographic conditions within many areas of Puget Sound likely result in the larvae staying within the basin where they are born rather than being more broadly dispersed by tidal action or currents (Drake *et al.*, 2010).

Larvae occur throughout the water column (Love *et al.*, 2002; Weis, 2004). When bocaccio and canary rockfish reach sizes of 1 to 3.5 in (3 to 9 cm) or 3 to 6 months old, they settle into shallow, intertidal, nearshore waters in rocky, cobble and sand substrates with or without kelp (Love *et al.*, 1991; Love *et al.*, 2002). This habitat feature offers a beneficial mix of warmer temperatures, food, and refuge from predators (Love *et al.*, 1991). Areas with floating and submerged kelp species support the highest densities of juvenile bocaccio and canary rockfish, as well as many other rockfish species (Carr, 1983; Halderson and Richards, 1987; Matthews, 1989; Love *et al.*, 2002). Unlike bocaccio and canary rockfish, juvenile yelloweye rockfish are not typically found in intertidal waters (Love *et al.* 1991; Studebaker *et al.* 2009), but are most frequently observed

in waters deeper than 30 meters (98 ft) near the upper depth range of adults (Yamanaka *et al.*, 2006).

Depth is generally the most important determinant in the distribution of many rockfish species of the Pacific coast (Chen, 1971; Williams and Ralston, 2002; Anderson and Yoklavich, 2007; Young *et al.*, 2010). Adult yelloweye rockfish, canary rockfish, and bocaccio generally occupy habitats from approximately 30 to 425 m (90 ft to 1,394 ft) (Orr *et al.*, 2000; Love *et al.*, 2002), and in Federal waters off the Pacific coast each species is considered part of the “shelf rockfish” assemblage under the authorities of the Magnuson-Stevens Fishery Conservation and Management Act because of their generally similar habitat usages (50 CFR part 660, Subparts C–G).

Adult yelloweye rockfish, canary rockfish, and bocaccio most readily use habitats within and adjacent to areas that are highly rugose (rough). These are benthic habitats with moderate to extreme steepness, complex bathymetry, and/or substrates consisting of fractured bedrock, rock, and boulder-cobble complexes (Yoklavich *et al.*, 2000; Love *et al.*, 2002; Wang, 2005; Anderson and Yoklavich, 2007). Most of the benthic habitats in Puget Sound consist of unconsolidated materials such as mud, sand, clays, cobbles and boulders, and despite the relative lack of rock, some of these benthic habitats are moderately to highly rugose. More complex marine habitats are generally used by higher numbers of fish species relative to less complex areas (Anderson and Yoklavich, 2007; Young *et al.*, 2010), thus supporting food sources for sub-adult and adult yelloweye rockfish, canary rockfish, and bocaccio. More complex marine habitats also provide refuge from predators, and their structure may provide shelter from currents, thus leading to energy conservation (Young *et al.*, 2010).

Though areas near rocky habitats or other complex structure are most readily used by adults of each species, non-rocky benthic habitats are also occupied. In Puget Sound, adult yelloweye rockfish, canary rockfish, and bocaccio have been documented in areas with non-rocky substrates such as sand, mud, and other unconsolidated sediments (Haw and Buckley, 1971; Washington, 1977; Miller and Borton, 1980; Reum, 2006).

Prey

Food sources for yelloweye rockfish, canary rockfish, and bocaccio occur throughout Puget Sound. However, each of the Basins has unique biomass and species compositions of fishes and

invertebrates, which vary temporally and spatially (Rice, 2007; Rice *et al.*, 2012). Absolute and relative abundance and species richness of most fish species in the Puget Sound/Georgia Basin increase with latitude (Rice, 2007; Rice *et al.*, 2012). Despite these differences, each Basin hosts common food sources for yelloweye rockfish, canary rockfish, and bocaccio as described below.

Larval and juvenile rockfish feed on very small organisms such as zooplankton, copepods and phytoplankton, small crustaceans, invertebrate eggs, krill, and other invertebrates (Moser and Boehlert, 1991; Love *et al.*, 1991; Love *et al.*, 2002). Larger juveniles also feed upon small fish (Love *et al.*, 1991). Adult yelloweye rockfish, canary rockfish, and bocaccio have diverse diets that include many species of fishes and invertebrates, including crabs, various rockfishes (*Sebastes spp.*), flatfishes (Pleuronectidae spp.), juvenile salmon (*Oncorhynchus spp.*), walleye pollock, (*Theragra chalcogramma*), Pacific hake (*Merluccius productus*), Pacific cod (*Gadus macrocephalus*), green sea urchin (*Stongylocentrotus droebachiensis*), lingcod (*Ophiodon elongates*) eggs, various shrimp species (*Pandalus spp.*), and perch (*Rhacochilus spp.*). Common forage fish that are part of their diets include Pacific herring (*Clupea harengus pallasii*), surf smelt (*Hypomesus pretiosus*), and Pacific sand lance (*Ammodytes hexapterus*) (Washington *et al.*, 1978; Lea *et al.*, 1999; Love *et al.*, 2002; Yamanaka *et al.*, 2006).

Summary of Public and Peer Review Comments Received and Responses

We solicited public comment for a total of 90 days on the proposed designation of critical habitat for the Puget Sound/Georgia Basin DPSs of yelloweye rockfish, canary rockfish and bocaccio. We received written comments from five commenters, and these are available online at: <http://www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2013-0105>. Summaries of the substantive comments received, and our responses, are organized by category and provided below.

In December 2004, the Office of Management and Budget (OMB) issued a Final Information Quality Bulletin for Peer Review pursuant to the Information Quality Act (IQA). The Bulletin was published in the **Federal Register** on January 14, 2005 (70 FR 2664). The Bulletin established minimum peer review standards, a transparent process for public disclosure of peer review

planning, and opportunities for public participation with regard to certain types of information disseminated by the Federal Government. The peer review requirements of the OMB Bulletin apply to influential or highly influential scientific information disseminated on or after June 16, 2005.

Two documents supporting this final designation of critical habitat for listed rockfishes are considered influential scientific information and subject to peer review. In accordance with the OMB policies and the Information Quality Act (IQA) (Section 515 of Public Law 106–554), we solicited pre-dissemination peer review of the draft Biological Report (NMFS, 2013a) from three reviewers. We also solicited peer review of the draft Economic Analysis (NMFS, 2013b) from two reviewers. We received two sets of peer review comments on the draft Biological Report in advance of proposing critical habitat for listed rockfishes, and they are included in the Peer Review Report (http://www.cio.noaa.gov/services_programs/prplans/ID213.html). Based on those peer review comments, we revised the Biological Report prior to our proposed designation. There was some overlap between the comments from the peer reviewers and the substantive public comments on the draft Biological Report (NMFS, 2013b). As many peer review and public comments were similar, we have responded to both the peer reviewer's comments and public comments below. We received no peer review responses on the draft Economic Analysis; however, we did receive public comments specific to economics. Responses to the public comments on the draft Economic Analysis (NMFS, 2013b) and also the draft Section 4(b)(2) Report (NMFS, 2013c) are included below. Revisions addressing the public comments have been made in the final documents supporting this designation as discussed below (i.e., Biological Report, Economic Analysis, and Section 4(b)(2) Report), and the final versions of those documents can be found on our Web site at: <http://www.wcr.noaa.gov/>.

Physical or Biological Features Essential for Conservation

Comment 1: One peer reviewer stated that the Biological Report provided an adequate review of listed rockfish life history attributes, the physical and biological features essential to conservation, and specific areas for designation. The reviewer stated that the lack of biological and life-history information for canary, yelloweye and bocaccio in Puget Sound restricts a more complete analysis of critical habitat

needs of these species, thus obligating a conservative approach to designating critical habitat. The reviewer asked how new scientific information will be used in the future to modify or refine critical habitat designation.

Response: This designation is based upon “best available science.” As new information relevant to, among other things, historical and contemporary habitat use is gathered and developed, we may revise this designation. In spring 2013 we appointed a Rockfish Recovery Team to aid in the development of the Recovery Plan for listed rockfishes. The Recovery Team is composed of nine individuals with a variety of academic and government affiliations and expert knowledge of listed rockfishes and the Puget Sound/Georgia basin ecosystem. That recovery team effort is underway and NMFS anticipates releasing a draft Recovery Plan for public review and comment in 2015.

Comment 2: One peer reviewer stated that a statistically-based predictive model would be the best case approach to scientifically define critical habitat for listed rockfish in Puget Sound. However, due to the lack of precise bathymetry and habitat information, the peer reviewer stated that the approach we used to identify critical habitat was a conservative, risk-averse approach to defining adult and juvenile habitat because it includes most records where listed rockfishes have been documented and areas they likely occupy.

Response: This designation is based upon “best available science.” We agree that a statistically-based predictive model, or similar approach, could provide a sophisticated assessment of important listed rockfish habitat, yet we do not have sufficient information to build such a model, and the ESA requires we meet statutory timeframes to designate critical habitat. We also agree with the commenter that the current bathymetry and habitat knowledge of most of the Puget Sound/Georgia Basin necessitates the use of the best available methods and analytical tools described in the Biological Report. In order to build a statistically-based predictive model to inform the development of critical habitat for listed rockfishes, we would need a combination of historical and contemporary population data, built from a new, systematically conducted survey across all likely habitat in the range of the DPSs, in addition to more sophisticated benthic habitat information. We expect that our draft Recovery Plan will outline the research and data needs to gain pertinent information to potentially develop such

a predictive model in the future. An example of a critical research task to build such a predictive model is systematic surveys targeting listed rockfish habitats in the Puget Sound. The Washington Department of Fish and Wildlife (WDFW) has conducted Remotely Operated Vehicle (ROV) surveys in the past several years for rare rockfishes in the San Juan Islands (Pacunski *et al.*, 2013). We are funding additional ROV surveys for other areas of the Puget Sound to build our knowledge on listed rockfish habitat use and population information.

Comment 3: One peer reviewer of our draft Biological Report (NMFS, 2013a) stated we should use maps generated by WDFW from surveys and historical sources to evaluate the effectiveness of our benthic habitat analytical tools at encompassing known occurrences of the adults within the DPSs.

Response: We did what the commenter requested. Prior to publishing the proposed critical habitat designation for listed rockfish we assessed the maps generated by WDFW and published in Palsos *et al.* (2009) to compare the documented locations of yelloweye rockfish, canary rockfish and bocaccio in the Puget Sound. As described in the final Biological Report (NMFS, 2014a), we assessed the number of listed rockfish observations located outside of areas of high rugosity, and found that most were included in our habitat evaluation methods. We added the few listed rockfish observations that fell outside of our initial critical habitat area, which resulted in 0.94 square miles (2.4 sq km) of area added to critical habitat (NMFS, 2014a).

Comment 4: One peer reviewer stated that there is a lack of specific knowledge about habitat requirements, life histories, and habitat occurrence of the listed rockfishes in the Puget Sound DPSs. The reviewer stated that it was logical of NMFS to draw from knowledge of habitat and life history requirements throughout the range of these species, but the Biological Report should better emphasize that there is a lack of direct information regarding the juvenile habitat requirements for canary and bocaccio rockfishes in Puget Sound and that what is known from coastal populations, especially from California, may not apply to the unique geomorphology and oceanography of the Puget Sound DPSs.

Response: We agree with the commenter that most of our knowledge regarding the life-history and habitat use of yelloweye rockfish, canary rockfish and bocaccio is based upon research of rockfishes that live in waters outside of the Puget Sound/Georgia Basin.

However, we must designate critical habitat based upon “best available science.” We revised our Biological Report in response to this peer review comment to further underscore the source of best science available to inform this designation and the status of our knowledge of listed rockfishes in Puget Sound.

Comment 5: One commenter stated that we did not consider some biological components of critical habitat, such as kelp and floating vegetation, and existing data supported their use.

Response: We did what the commenter suggests. In our proposed designation we considered the biological components of rockfish habitat including biotic benthic communities that consist of kelp, and we report these general conditions for each of the main Basins of the Puget Sound in our final Biological Report (NMFS, 2014a). Our analysis of the features in nearshore areas that are important for canary rockfish and bocaccio considered the location of documented kelp and areas where kelp can be supported by appropriate substrates such as cobbles and rock. We agree that floating vegetation such as detached eelgrass and kelp are important for juvenile rockfish, but were unable to map areas of floating vegetation because their locations are likely extremely ephemeral and generally unpredictable with existing analytical tools.

Comment 6: One commenter questioned the designation of critical habitat in South Puget Sound and stated that there is a high prevalence of unvegetated mudflats in this region which would be inappropriate habitat for listed rockfish.

Response: We agree that there is a high prevalence of unvegetated mudflats in this Basin which would be inappropriate critical habitat for listed rockfishes. During our analysis of habitats in South Puget Sound we found that much of the most southern portion of the Basin does not have nearshore habitat features such as kelp readily used by rearing canary rockfish and bocaccio. Thus our designation of critical habitat does not include these areas of the South Puget Sound, but does include other nearshore areas of the basin that support kelp and/or have substrates that can support kelp and otherwise have beneficial rearing conditions.

Comment 7: One commenter stated that data exist to allow us to conduct a tiered “grading” of biological parameters, such as forage fish species, and features in each of the Basins of Puget Sound in order to provide an

overview of the differences between each area.

Response: Our draft and final Biological Reports (NMFS, 2013; 2014a) provide a qualitative description of the biological parameters, or essential features, relevant to listed rockfishes in each of the Basins of the Puget Sound. We do not believe the generally coarse and uneven level of information we have on many biological parameters important to listed rockfishes in each of the Basins of Puget Sound is of sufficient quality to inform a grading system for this final critical habitat designation. We will continue to evaluate the usefulness of this approach as new information becomes available.

Specific Areas Within the Geographical Area Occupied by the Species

Comment 8: One commenter noted that the proposed designation does not constitute the entire geographical area which can be occupied by the listed species, or which is currently occupied.

Response: We agree that this critical habitat for listed rockfishes does not cover the entire geographic area of the Puget Sound/Georgia Basin, nor the entire area likely to be currently occupied by each species. Section 3(5)(A) of the ESA directs us to designate “specific areas” occupied by the species with physical or biological habitat features essential to the conservation of the species. Additionally, ESA Section 3(5)(C) provides “[e]xcept in those circumstances determined by the Secretary, critical habitat shall not include the entire geographical area which can be occupied by the threatened or endangered species.”

Comment 9: One commenter noted that critical habitat should be specifically identified for the larval stages of listed rockfishes. The commenter noted research by LeClair *et al.* (2012) on larval rockfishes in Puget Sound and suggested that modeling approaches could be used to model larval dispersal and support identification of critical habitat.

Response: The ESA requires that we base this designation on “best available science.” We currently do not have sufficient information regarding the habitat requirements of larval listed rockfishes to determine which features are essential for conservation, and thus do not designate critical habitat based on the life-history requirements and habitats used by this life-stage. Because larval rockfishes are nearly impossible to identify to species visually until they are several months old (Love *et al.*, 2002), there is relatively little known about their life-history on a species-

specific level. Our knowledge of larval rockfishes in Puget Sound is similarly limited to a handful of studies that report the location, densities and presence during portions of the year (e.g., Waldron, 1972; Busby, 2000; Chamberlin *et al.*, 2004; Weis, 2004; Greene and Godersky, 2012). None of the studies that took place in Puget Sound provided information specifically regarding the habitat use of larval yelloweye rockfish, canary rockfish or bocaccio. Larval rockfish species survival and settlement are dependent upon the vagaries of climate, abundance of predators, oceanic currents, and chance events, and we do not know the relative importance of these factors in the Puget Sound/Georgia Basin (Drake *et al.*, 2010). LeClair *et al.*'s (2012) research on the settlement of brown rockfish (*Sebastes auriculatus*) in Puget Sound determined that some larval brown rockfish returned to the same habitat as their parents, indicating that site-fidelity may be influenced by behavior and local oceanic conditions. Modeling for larval rockfish dispersal in Alaskan waters was published by Stockhausen and Hermann (2007), and this type of research can certainly inform scenarios in which larval rockfishes are released and their potential ultimate recruitment areas tracked, and deserve additional analysis for the unique waters of Puget Sound. However, these modeling methods have not yet been adapted for the multiple Basins of Puget Sound and thus are not available to inform our designation of critical habitat. The development of such larval dispersal models will likely be identified as a priority action in the draft rockfish Recovery Plan.

Though we did not formulate our designation of critical habitat based on the life-history requirements of larval listed rockfishes, we note that some of the waters of Puget Sound used by this life-stage are nonetheless designated as critical habitat for listed rockfishes. The final critical habitat designation includes not only the benthic features with the specific designated areas, but also the marine waters above these habitats within these areas. As indicated by the inclusion of water quality as an essential feature in our proposed rule, we did intend for the designation to include not just the benthic substrate in the areas proposed, but also the water above it that is used by larval listed rockfishes.

Comment 10: One peer reviewer stated that juvenile yelloweye rockfish are often observed in depths from 20 to 30 m (65 to 98 ft) and this habitat was not included in the proposed critical habitat designation. The reviewer

recommended that we expand juvenile yelloweye rockfish habitat to include waters up to 20 m in depth.

Response: Based on review of the life-history of yelloweye rockfish, we found there are relatively few documented occurrences of yelloweye rockfish in this shallower range outside or inside the Puget Sound/Georgia Basin. Juvenile yelloweye rockfish do not typically occupy intertidal waters (Love *et al.*, 1991; Studebaker *et al.*, 2009). A few juveniles have been documented in shallow nearshore waters (Love *et al.*, 2002; Palsen *et al.*, 2009; Cloutier, 2011), but most settle in habitats in waters greater than 30 m (98 ft) (Richards, 1986; Yamanaka *et al.*, 2006). One study found juvenile yelloweye rockfish have been observed at a mean depth of 73 m (239 ft), with a minimum depth of 30 m (98 ft) in waters of British Columbia (Yamanaka *et al.*, 2006). As such, though juvenile yelloweye rockfish occasionally occupy waters shallower than 30 meters, best available science does not support findings that waters shallower than 30 meters have features that are essential to the conservation of the species.

Comment 11: WDFW questioned the designation of critical habitat in South Puget Sound and stated there are no data suggesting that adult populations occur in the area.

Response: We disagree. Existing scientific research documents that adults of each species utilized the South Puget Sound historically. Reports by the Washington Department of Fish from the 1960s and 1970s (i.e., Bargman, 1977; Buckley, 1965; 1966; 1967) documented thousands of yelloweye rockfish, canary rockfish, and bocaccio caught by recreational anglers in the South Puget Sound area. There have not been recent scientific surveys for rockfish in the South Puget Sound area, but it is very likely that each species continues to persist at depressed levels of abundance in this area. Given the long life-span of listed rockfishes, the cohorts (and subsequent generations) of the fish documented by Bargman (1977) and Buckley (1965, 1966, 1967) very likely continue to live in the South Puget Sound. Catch estimates from WDFW indicate that in recent years recreational anglers targeting salmon and bottomfish continue to catch canary rockfish in Marine Catch Area (MCA) 13, which includes areas south of the Tacoma Narrows, and a few bocaccio and yelloweye rockfish have been caught by anglers targeting salmon in MCA 11, which includes waters north of the Tacoma Narrows (WDFW, 2011).

Comment 12: One commenter questioned the designation of nearshore

habitat for canary rockfish and bocaccio in several areas of Puget Sound. They stated that waters on the west side of Bainbridge Island were proposed for designation despite the relative lack of adult canary rockfish and bocaccio documented there. Finally, they stated that a large portion of Bellingham Bay is "mud," implying that areas with this substrate are not appropriate rockfish habitat.

Response: We proposed water shallower than 30 m (98 ft) on the west side of Bainbridge Island as nearshore critical habitat for canary rockfish and bocaccio, and waters deeper than 30 m in this area as deepwater critical habitat for all listed rockfishes. The final critical habitat designation for listed rockfishes is consistent with the proposed rule and includes critical habitat designation in portions of the west side of Bainbridge Island, and some of Bellingham Bay. For juvenile canary rockfish and bocaccio using the nearshore, we assessed the characteristics and features of specific areas of each Basin to determine the suitability of substrates that provide beneficial rearing conditions.

We agree with the commenter that there is a lack of documented occurrences of canary rockfish on the west side of Bainbridge Island (bocaccio have been documented there), but each species has been documented in waters near Bainbridge Island. Since our knowledge about the historical or contemporary locations of listed rockfishes is hindered by the lack of systematic surveys in most of the Basins of the Puget Sound, we assessed the evidence that the species occupied the Basin, and the habitat characteristics of particular areas of each Basin, as described in our final Biological Report (NMFS, 2014a). Our final designation of the nearshore area of Bellingham Bay does not include many acres of unconsolidated sediment near the Nooksack River delta that are unlikely to provide beneficial rearing conditions for canary rockfish and bocaccio, in part because of the lack of suitable substrates to support kelp (NMFS, 2014a).

Comment 13: WDFW noted that it, in addition to the Seattle Aquarium, has documented young of the year rockfishes in SCUBA surveys at sites throughout Puget Sound for several years and that this information should be used to increase the confidence in the validity of assumptions about what constitutes appropriate juvenile habitat in the nearshore.

Response: We acknowledge that organizations such as the Seattle Aquarium, WDFW, the Reef Environmental Education Foundation

(REEF), and others have conducted important surveys for rearing rockfishes in Puget Sound. We were unable to integrate these surveys into an assessment of nearshore conditions and habitat preferences for yelloweye rockfish, canary rockfish or bocaccio for several reasons. First, the identification of young of the year rockfish to species is imprecise, with many species having similar color and shape (Love *et al.*, 2002). Second, these surveys are limited spatially and temporally. Aside from WDFW data reported in Palsson *et al.* (2009) and Tonnes (2012), WDFW has not published much of its previous nearshore surveys for juvenile rockfishes. For these reasons we found it difficult to draw conclusions about listed rockfish rearing habitat from previous research identified by WDFW, given the imprecise species identification, limitations of the surveys, and relative lack of reported information.

Comment 14: One commenter stated that we proposed to designate critical habitat in some degraded areas and that these areas will “require restoration before it [they] can be fully used by listed rockfish.” They specifically mentioned Sinclair Inlet, Commencement Bay, and Elliot Bay, and that we should include data on pollution in these areas.

Response: Our proposed and final designation of critical habitat for listed rockfishes include areas that are degraded by a variety of sources, and our description of each of the Basins of Puget Sound provides a discussion of the biological condition of the Basins. In our proposed and final designation we include a table in the Biological Report (NMFS, 2013; 2014a) of areas with contaminated sediments, including Sinclair Inlet, Commencement Bay, and Elliot Bay. In our final Biological Report (NMFS, 2014a) we state that a reduction of contaminant input and clean-up of sediments will be necessary to protect listed rockfishes and their food sources. Despite the degraded conditions of Sinclair Inlet, Commencement Bay and Elliot Bay, we do not know of environmental conditions that would preclude the full use of these waters by listed rockfishes. We note that waters in Sinclair Inlet Navy Restricted Area were not proposed as critical habitat for listed rockfishes (see Appendix C of our section 4(b)(2) report).

Delineating and Mapping Areas To Identify Critical Habitat

Comment 15: We had several comments on our GIS methods to aid our determination of specific areas with essential features, particularly in waters

deeper than 30 meters. One commenter stated that our methods to identify critical habitat were sound, but stated that our GIS methods to designate habitats around complex seafloors resulted in some areas that are “unsuitable habitat.” Similarly, one peer reviewer requested that our GIS procedures be further explained.

Response: As detailed in subsequent portions of this final rule and our final Biological Report (NMFS, 2014a), we have revised our GIS methods to update the final critical habitat designation. In the proposed and final designation, our analysis of areas that contain essential features for yelloweye rockfish, canary rockfish and bocaccio deeper than 30 meters was in part determined by assessing where areas of increased seafloor complexity occur. Habitats with higher complexity are more likely to be used by adult yelloweye rockfish, canary rockfish, and bocaccio because these areas provide opportunity for forage and refuge.

In our proposed critical habitat designation we determined relative seafloor complexity by using the rugosity tool (used in the Benthic Terrain Modeler (BTM) version compatible with ArcGIS 9.3), which was calculated as the ratio of surface area to planar area (Kvitek *et al.*, 2003; Dunn and Halpin, 2009). In the final rule, consistent with “best available science,” we use an updated rugosity tool to locate where the essential feature of complex (rugose) seafloor occurs (available with the BTM under ArcGIS 10.2). The updated rugosity tool was generated by running the terrain Vector Rugedness Measure (VRM) script developed by Sappington *et al.* (2007). We used this updated tool to determine rugosity because it better detects relevant seafloor complexity than the rugosity tool used in the proposed rule. The VRM quantifies terrain ruggedness and seafloor complexity differently than the ArcGIS 9.3 rugosity tool by differentiating smooth, steep topography from topography that is irregular and varied in gradient and aspect (Sappington *et al.*, 2007). Some areas of mapped high rugosity differ from the proposed designation because we used updated gridded depth data created by the Nature Conservancy to identify the 30-meter depth contour (Greene and Aschoff, 2014). As a result of the new rugosity tool and bathymetry data, some of the smooth and steep slopes proposed as critical habitat have been removed in the final designation, while other areas that were not proposed now meet the definition of critical habitat and have been added. The net result is a 28 percent reduction in the deepwater

habitat area designated for listed rockfishes based on the best available rugosity tools.

Our proposed and final GIS methods resulted in the designation of some habitats that are adjacent to areas of high rugosity. The designation of these areas next to highly rugose habitats is supported by our understandings of the life history of yelloweye rockfish, canary rockfish and bocaccio, including movement of adult fish and ontogenetic movement. While most of these habitats near areas of high rugosity likely consist of unconsolidated materials such as mud and sand mixtures, yelloweye rockfish, canary rockfish and bocaccio have been documented in these types of habitats within and outside of the Puget Sound Georgia Basin (NMFS, 2014a). In Puget Sound, adult yelloweye rockfish, canary rockfish, and bocaccio have been documented in areas with non-rocky substrates such as sand, mud, and other generally unconsolidated sediments (Haw and Buckley, 1971; Washington, 1977; Miller and Borton, 1980; Reum, 2006). Surveys from outside the range of these DPSs also have documented each species in relatively less complex habitats, though generally on a less frequent basis than more complex habitats. Yelloweye rockfish have also been documented in areas with mud and mud/cobble habitats in waters off the coasts of Washington (Wang, 2005), California (Yoklavich *et al.*, 2000), Oregon (Stein *et al.*, 1992), and British Columbia, Canada (Richards, 1986), and have been observed adjacent to large and isolated boulders in areas of flat and muddy bottoms in Alaskan waters (O’Connell and Carlile, 1993). Canary rockfish were found to be slightly more abundant in less complex habitat than more complex habitat off the Washington coast (Jagiello *et al.*, 2003). Wang (2005) also observed canary rockfish in a variety of benthic habitats off the Washington coast. Canary rockfish were most frequently found near boulders, but were also found near benthic habitats consisting of sand, mud, and pebble mixtures (Wang, 2005). Johnson *et al.* (2003) reported that approximately 15 percent of canary rockfish were observed over soft-bottomed habitats in surveys in Alaska. Bocaccio also occupy benthic areas with soft-bottomed habitats, particularly those adjacent to structure such as boulders and crevices (Yoklavich *et al.*, 2000; Anderson and Yoklavich, 2007).

Comment 16: One commenter stated we should evaluate our GIS methods to designate areas near high rugosity by assessing listed rockfish foraging, predation and home-range behavior, gene flow, and population isolation.

Response: In assessing appropriate GIS methods to designate critical habitat we accounted for the life-history of listed rockfishes, but not explicitly for gene flow or population isolation. As previously mentioned, listed rockfishes display ontogenetic movement as they grow and thus can use a variety of habitat types, such as those near habitat of high rugosity, as they mature. Similarly, some adult canary rockfish and bocaccio have been documented to move long distances (Demott, 1983; Love *et al.*, 2002; Friedwald, 2009), indicating these two species occupy habitats not immediately adjacent to the seafloor with high rugosity. We are not aware of information regarding gene-flow or population isolation that would assist in determining critical habitat areas for listed rockfishes. These attributes are important when considering whether a population qualifies as a DPS, developing recovery measures, and assuring the long-term viability of listed rockfishes. However, doing so requires securing additional research and analytical tools not available within the statutory timeframes to designate critical habitat. However, this effort will likely be outlined in the draft Recovery Plan.

Comment 17: Several commenters and both peer reviewers questioned our use of the value of 1.005 and above to define “high rugosity” benthic habitats in Puget Sound to assist in identifying specific areas for adult listed rockfishes. One commenter stated that this value is related to fish presence/absence information and not fish density information.

Response: As mentioned above, we updated our GIS methods to help determine final critical habitat designations for listed rockfishes. In ArcGIS 10.2 we used an updated rugosity tool that is less dependent upon the slope of the habitat, and more dependent on a quantification of terrain ruggedness by measuring the dispersion of vectors orthogonal to the terrain surface. We used a rugosity value of 0.001703 and above to define areas of “high rugosity” and note that, because of the updated methodology, the new rugosity value is not scaled to the original value of 1.005.

Our use of this rugosity threshold and additional GIS procedures was informed by habitat characteristics mapped by Greene and Barrie (2007) in the San Juan Basin, additional data reported in Palsson *et al.* (2009) and general life-history literature summarized in our Biological Report (NMFS, 2014a), as well as listed rockfish presence/absence information.

Comment 18: One peer reviewer stated that our application of the BTM appeared to include as proposed critical habitat benthic areas with muddy substrates that likely do not contain rock or boulders due to the fjord-like nature of Puget Sound. The reviewer stated that a method to improve our application of the BTM would be to use current speed information, which would potentially reduce the areas that consist of silt-mud.

Response: Our application of the BTM did result in the designation of some non-rocky habitats in the Puget Sound. As mentioned in our draft and final Biological Report (NMFS, 2013; 2014a) and above, yelloweye rockfish, canary rockfish and bocaccio have been documented to use non-rocky habitats within the range of these DPSs and outside of the range of these DPSs, though typically at lower density than rocky habitats. In response to the reviewer’s comment, we received modeled average bottom current speed estimates for Puget Sound from the Pacific Northwest National Laboratory and assessed its utility to assist us in evaluating listed rockfish habitat. We found that the scale of the modeled current velocity data was too large to provide useful information to elucidate possible associations with bottom substrate compositions. We also found that listed rockfishes have been documented in areas with relatively slow average bottom currents. For example, in areas such as Hood Canal the bottom velocities can be very slow, yet listed rockfishes have been documented in multiple areas of this Basin. Thus we did not find a useful relationship between bottom current information and habitat to assist with evaluating listed rockfish habitat.

Comment 19: One peer reviewer stated that the BTM was imprecise at identifying juvenile habitat in shallow water <30 m (98ft) that consisted of sand, cobble, and rock, and that our use of the ShoreZone database to predict subtidal substrates from intertidal ones may not be an appropriate tool. The reviewer stated that shorelines consisting of sand, cobble, or even rock can transition to muddy or silty environments in deeper waters which are not predicted by the shoreline character, and that this can be especially the case in the inner and eastern San Juan Islands and in south Puget Sound. The reviewer also mentioned that our proposed nearshore critical habitat designation for canary rockfish and bocaccio in the heads of non-estuarine embayments such as Case, Carr, and Dyes Inlets, Port Madison, Sinclair Inlet, Penn Cove, Discovery Bay, and Port

Townsend Bay are areas that likely do not support kelp. The reviewer stated that a better test would have been to check our proposed designation in the nearshore with the historical NOAA bottom substrate database that has been shared among Puget Sound researchers and also occurs on several of the fine-scale nautical charts of Puget Sound.

Response: We used the Washington State Department of Natural Resources’ (DNR) ShoreZone inventory to identify substrates that host or may support the growth of kelp. Unlike in waters deeper than 30 meters, we did not use the BTM to identify benthic habitats with high rugosity in the nearshore. We did use the benthic habitat classifications of the BTM related to the locations where moderate to large rivers enter Puget Sound and found that many of these areas do not support kelp and possess habitats beneficial for rearing juvenile canary rockfish and bocaccio. We agree with the reviewer’s comment that shorelines consisting of sand, cobble, or even rock can give way to muddy or silty environments not predicted by the shoreline character—this is one of the limitations of a shoreline inventory based on aerial surveys. However, even without the presence of kelp, juvenile canary rockfish and bocaccio have been found to rear in sandy areas and areas within and adjacent to complex substrates. Because the ShoreZone surveys were done aerially, and during different seasons, they were relatively imprecise at identifying all of the areas where kelp can grow. Based on the reviewer’s suggestion, we reassessed our proposed designations of the above mentioned inlets and bays. We found that portions of Case, Carr and Dyes Inlets, Port Townsend Bay, Sinclair Inlet, and Port Madison are documented as supporting kelp by the ShoreZone inventory. We found that Discovery Bay also supports kelp, but note in our proposed and final designation we did not designate the southern-most portion of this Bay where freshwater enters, as this area is not likely to support essential features for rearing canary rockfish and bocaccio (as described in our final Biological Report (NMFS, 2014a)). Penn Cove was not documented as supporting kelp according to the ShoreZone inventory, but has substrate types that can support kelp and also has other substrates used by juvenile canary rockfish and bocaccio. Based on our reassessment we made no adjustment to the final critical habitat designation in Penn Cove or any of the other bays and inlets specifically mentioned by the reviewer.

Comment 20: One peer reviewer stated that another improvement to our

designation methodology would be to use WDFW research bottom trawl data or other information to model fish communities in terms of hard or soft-bottom types that could help predict where listed rockfishes are more likely to occur.

Response: We found that the study design and sampling locations of WDFW bottom trawl research do not provide sufficient information for evaluating listed rockfish habitats as suggested by the peer reviewer. Data from WDFW trawl survey are depth stratified and sampling has been done in twelve regions of Puget Sound. Past WDFW trawl sampling effort was episodic with some regions sampled infrequently, only once, or only at the beginning or the end of the survey (Drake *et al.*, 2010). Sampling effort was also uneven with some regions having as few as two replicate hauls in a depth zone in a given year, while others may have had as many as 25 replicate hauls. The lack of consistent and sufficient replicate sampling reduces the value of the past trawl surveys for rockfish habitats. Further, much of the rocky and/or complex habitat used by listed rockfishes is not effectively sampled by trawl gear, compared to unconsolidated habitat that can be easily surveyed. For these reasons we found it difficult to draw reliable conclusions about listed rockfish habitat from WDFW bottom trawl data.

Comment 21: One commenter stated that we should improve the designation of critical habitat by using enhanced modeling and gathering additional data by field verification of model predictions prior to final critical habitat designation. They noted that additional research, such as various surveys, are needed and critical habitat designation should be postponed until more data are available.

Response: To designate critical habitat the ESA requires that we act within a specific time frame and use the best available information. We researched and reviewed the best available data on listed rockfish, including recent biological surveys, geological surveys, reports, peer-reviewed literature and public comments, which are summarized in our final Biological Report (NMFS, 2014a). Nonetheless, we agree with the commenter that additional fishery-independent research projects, such as ROV surveys, are essential to fill additional information needs and inform recovery implementation. Importantly, these surveys should be designed to sample likely listed rockfish habitats (i.e., similar to Pacunski *et al.*, 2013), rather than recent stereological surveys

conducted by WDFW that sample habitat based on a gridded system that does not explicitly account for habitat types or depth. We continue to support future surveys and will reevaluate this designation if necessary as additional scientific information becomes available.

Comment 22: One commenter noted our comparison of Greene *et al.*'s (2007) high-resolution bathymetric mapping of portions of the San Juan Basin with the areas of rugosity identified by the BTM, and recommended that we conduct a similar comparative procedure within other areas of Puget Sound.

Response: The high-resolution benthic habitat maps produced by Greene *et al.* (2007) only exist for portions of the San Juan Basin. We are therefore unable to conduct an analogous assessment across the rest of the Puget Sound. The United States Geological Survey is in the process of developing high resolution benthic maps across much of the Puget Sound, but these maps are not yet published or available to potentially refine critical habitat designation for listed rockfishes in other Basins.

Comment 23: One commenter stated that some of the steep slopes we propose as critical habitat are known as "not suitable" rockfish habitat as determined by their observations through drop camera and ROV surveys, and recommended that we use current and historical distribution data for listed species to determine the suite and range of BTM metrics to calibrate a habitat suitability model.

Response: We used all available data on rockfish observations to inform critical habitat, but existing data are not sufficient to calibrate a habitat suitability model as suggested. WDFW has conducted drop camera surveys in various areas across the Puget Sound and many of these observations are reported in Palsson *et al.* (2009), which did inform our critical habitat designation. Other drop camera and ROV surveys have occurred in Puget Sound, but the results of these observations have not been published in reports and are not available. Because of the lack of historical or contemporary systematic surveys for rockfishes in most of the Puget Sound Basins, and the lack of comprehensive fishery data that provide relatively precise data on the location these species were caught, we are not confident that the observational data we have for yelloweye rockfish, canary rockfish and bocaccio fully explain their habitat usage sufficiently to justify the further development of a habitat suitability model at this time. We agree that additional and more

precise analysis of habitats used by listed rockfishes should be conducted as additional data are collected and analyzed. Additional surveys and analysis for rockfishes and habitat use are likely to be prioritized in the listed rockfish Recovery Plan and may be sufficient to develop a more sophisticated habitat suitability model in the future.

Comment 24: One peer reviewer stated that we should reevaluate a habitat ranking approach, as we have done for some Pacific salmonid critical habitat, to identify "special areas" of critical habitat. The reviewer pointed to habitats north of Orcas Island and Tacoma Narrows as areas as qualifying as "special areas."

Response: We considered a habitat ranking approach for designating critical habitat for listed rockfishes similar to our 2005 critical habitat designations for listed Evolutionarily Significant Units of Pacific salmonids, where we designated critical habitat areas as having "high," "medium," and "low" conservation value (70 FR 52630; September 2, 2005). Unfortunately, we found that the uneven resolution of benthic habitat mapping within the Puget Sound, in conjunction with the general lack of systematic historical or contemporary surveys for listed rockfishes in most of the Basins of Puget Sound, were not sufficient to support a habitat valuation approach as we did for salmonids. Collecting additional data and developing a habitat suitability model based on new benthic habitat data, fish surveys, and other pertinent information will likely be a priority task in the draft rockfish Recovery Plan.

Special Management Considerations

Comment 25: One peer reviewer asked how the special management considerations were identified.

Response: We identified the 11 special management considerations by assessing the types of ESA section 7 (a)(2) consultations we have conducted since the listing of yelloweye rockfish, canary rockfish and bocaccio in 2010, and the types of actions we consulted on for listed salmonids in Puget Sound prior to 2010 (NMFS, 2014a). In addition, we assessed other potentially non-federal actions that may have an effect on habitat by researching local rockfish reports such as Palsson *et al.* (2009) and Washington's rockfish recovery plan (WDFW, 2011a), and additional scientific data and research which identified suites of actions that can affect rockfish habitat in Puget Sound.

Comment 26: One peer reviewer stated that kelp harvest is limited in

Puget Sound and almost exclusively occurs in intertidal waters, where there is an unlikely threat to juvenile canary rockfish or bocaccio.

Response: Kelp harvest is regulated by WDFW and DNR and we are not aware of any commercial harvest of kelp in the Puget Sound at this time. We included kelp harvest as a special management consideration because the harvest of kelp could nonetheless affect the habitat quality for canary rockfish and bocaccio as each can rear in these areas.

Comment 27: One commenter stated that dredging and disposal of dredge materials are separate activities with separate management considerations.

Response: We agree with the commenter that the disposal of dredge material has different effects than the actual dredging of materials, and thus management considerations for each activity are unique. We have clarified within our Biological Report (NMFS, 2014a) that these are activities with distinct management considerations.

Comment 28: One peer reviewer stated that under the aquaculture special management consideration we should discuss additional habitat effects such as the hardening of intertidal and subtidal habitats by the addition of non-native oyster shells, gravel, and PVC tube for clam and oyster aquaculture.

Response: We agree with the commenter and have added additional language in our final Biological Report about the potential habitat effects of intertidal aquaculture operations.

Comment 29: One commenter stated that readers of the draft Biological Report could easily conclude that contaminated sediments are being disposed at open-water sites.

Response: We have revised the Biological Report (NMFS, 2014a) to more clearly state that contaminated sediments are more likely to be mobilized within the water column during dredging projects rather than disposal projects, and that sediments undergo analysis prior to disposal. We also note that sediment deemed too contaminated for open-water disposal by management agencies is placed in upland areas to avoid aquatic contamination. However, we note that some disposed sediments are not completely contaminant-free, rather they have been deemed as clean enough to allow open-water disposal.

Comment 30: One commenter stated that new information is essential to improving management and permitting of activities, such as shoreline armoring, in order to avoid, minimize, mitigate or predict adverse effects to listed rockfishes. The same commenter stated that additional data are needed to

describe the processes and structures that create and maintain rockfish habitat along Puget Sound shorelines.

Response: We agree that additional data that assesses how and where juvenile canary rockfish and bocaccio use nearshore habitats would improve our understanding of how shoreline projects may directly alter rockfish habitat. We disagree, however, with the premise that new information is necessary to provide guidance to management of currently proposed activities to avoid, minimize, mitigate or predict adverse effects from shoreline projects to rockfish habitat in the Puget Sound. Juvenile canary rockfish and bocaccio primarily use areas among and near various species of kelp. A WDFW report found that the disruption of submerged aquatic vegetation like kelp could threaten habitat quality of juvenile rockfish (Palsen *et al.*, 2009). Shoreline modification in Puget Sound includes activities such as bulkheading, filling, installation of overwater structures, and boat ramps (Palsen *et al.*, 2009). Man-made structures adjacent to rockfish habitats could diminish the value of the nearshore habitat used by rockfishes (Palsen *et al.*, 2009) by changing shoreline sediment dynamics, and removing or shading kelp habitats (Mumford, 2007). These types of nearshore projects can also harm forage fish habitats, such as those supporting surf smelt (Rice *et al.*, 2006) that are likely important food sources for listed rockfishes. As such, we believe that there is sufficient scientific information to regulate shoreline activities in ways to avoid, minimize, mitigate and predict adverse effects to listed rockfishes and their habitats and note that many of these measures are already recommended by local salmon recovery plans and technical documents commissioned by WDFW and others (e.g., Brennan *et al.*, 2009).

Comment 31: One commenter requested that we clarify that scientific research projects in Puget Sound which we identified as a special management consideration have only low level effects and occur under NMFS Section 10 permitting.

Response: We agree. Research that may take listed fish is reviewed and approved by NMFS under Section 10 (a)(1)(a) of the ESA. In the course of these reviews we have found that many research projects have little or no potential to result in more than short-term alterations to habitat of listed rockfishes. For instance, many of the trawl survey stations used by WDFW would occur outside of designated critical habitat for listed rockfishes, and other research projects conducted by

SCUBA, ROV or drop cameras would have no potential to alter critical habitat on a short or long-term basis.

Comment 32: WDFW requested that, under the fisheries special management consideration, we consider only fisheries currently underway in Puget Sound rather than those that have recently been closed.

Response: We acknowledge that fisheries within Puget Sound are dynamic—some are closed and re-opened seasonally and when markets develop, thus making them economically viable. For this reason we characterized the fishery special management consideration to include some fisheries that are closed, as it is possible that these fisheries might be proposed again in the foreseeable future by State and/or tribal fishery managers.

Comment 33: WDFW noted that the forage fish drag seines and lampara nets are currently used in Puget Sound, and there is no record of these methods catching listed rockfishes.

Response: The designation of critical habitat for listed species is designed to assist us in reviewing the effects of various actions on specific areas that have physical and biological features essential to the conservation of the species. In the case of listed rockfishes, we found essential features to include water quality, rugosity, and certain nearshore features. Special management considerations for fisheries consider only fishing methods that have the potential to alter critical habitat, rather than the specific impacts associated with catching a listed rockfish. Thus a particular fishing method, such as the lampara net fishery, may have little or no potential to catch an individual yelloweye rockfish, canary rockfish or bocaccio, but may nonetheless affect critical habitat. While the forage fish drag seine and lampara net fisheries may not catch listed rockfishes, they could affect physical and biological features of designated critical habitat, particularly if nets are lost.

Comment 34: WDFW noted that Hood Canal has been closed to bottomfishing since 2004, and questioned why fisheries are still noted as a special management consideration there.

Response: Recreational bottomfishing is currently closed in Hood Canal, but could be reopened at some point in the future. Other Hood Canal fisheries continue and can affect critical habitat, such as recreational and commercial shrimp and crab fishing, and the use of gill nets that, when lost, can harm benthic areas used by rockfishes (Good *et al.*, 2010) and designated as critical habitat.

Comment 35: Without providing how it should be considered in the designation, one commenter requested that the final critical habitat rule consider anthropogenic noise in Puget Sound, and noted that noise in some waters of Puget Sound is increased by vessel traffic and Navy exercises as reported by Basset *et al.* (2006). The commenter identified literature that reported effects of noise on hearing loss and behavior of some fish species.

Response: We acknowledge that noise can affect fish behavior and may affect the various life-stages of listed rockfishes, as has been documented in other reef fishes (Holles *et al.*, 2013), and that some of the Puget Sound has elevated noise from a variety of human sources. We have revised our Biological Report (NMFS, 2014a) to include descriptions of underwater noise in some of the Basins of the Puget Sound. Underwater sound may have a variety of effects on fish (Popper and Hastings, 2009), but there is a general dearth of research regarding the effects of noise on the behavior and health of rockfishes (but see Pearson *et al.*, 1992). Several of the special management considerations can result in elevated under water noise, including nearshore development and in-water construction, under water construction and operation of alternative energy hydrokinetic projects and cable laying, artificial habitat creation, and possibly dredging and disposal of dredged material. As such, we regularly conduct ESA section 7 consultations on construction activities that generate noise using best available science, and in these consultations measures are typically included to minimize or avoid direct impacts to ESA-listed species, including yelloweye rockfish, canary rockfish and bocaccio. Future section 7 consultations that include noise-generating activities will continue to assess the potential for exposure and effects to listed rockfishes within the range of these DPSs. Assessing the effects of anthropogenic noise on rockfish behavior and health will likely be identified as a task in the draft rockfish Recovery Plan.

Comment 36: Two commenters stated that our list of special management considerations should include ocean acidification (OA) and global climate change. They stated that the potential direct effects of these pressures on rockfishes are poorly understood, but that predictions about food web impacts and ecosystem-wide changes in habitat quality are available.

Response: A recent report found that climate change in the Northwest, including sea level rise, coastal erosion, and increasing ocean acidity, poses

major risks to the local marine environment (U.S. Global Change Research Program, 2014). We agree that climate change, sea-level rise (SLR), and OA have the potential to result in fundamental alterations to habitats and food sources of listed rockfishes, and we have added activities that lead to global climate change as a special management consideration. In a study published after we proposed critical habitat for listed rockfishes, OA was found to affect juvenile rockfish behavior (Hamilton *et al.*, 2014). Behavior (characterized as “anxiety” by the researchers) significantly changed after juvenile Californian rockfish (*Sebastes diploproa*) spent 1 week in seawater with the OA conditions that are projected for the next century in the California shore. The study indicated that OA could have severe effects on rockfish behavior (Hamilton *et al.*, 2014). Research conducted to understand adaptive responses to OA of other marine organisms has shown that although some organisms may be able to adjust to OA to some extent, these adaptations may reduce the organism’s overall fitness or survival (Wood *et al.*, 2008).

Aside from OA, future climate-induced changes to rockfish habitat could alter their productivity (Drake *et al.*, 2010), and affect their habitats from sea-level rise. Harvey (2005) created a generic bioenergetic model for rockfishes, showing that their productivity is highly influenced by climate conditions. For instance, El Niño-like conditions generally lowered growth rates and increased generation time. The negative effect of the warm water conditions associated with El Niño appear to be common across rockfishes (Moser *et al.*, 2000). Recruitment of all species of rockfish appears to be correlated at large environmental scales. Field and Ralston (2005) hypothesized that such synchrony was the result of large-scale climate forcing. Exactly how climate influences rockfishes in Puget Sound is unknown; however, given the general importance of climate to rockfish recruitment, it is likely that climate strongly influences the dynamics of ESA-listed rockfish population viability (Drake *et al.*, 2010).

Global sea level has risen by an average of 0.067 inch \pm 0.012 inch per year (1.7 \pm 0.3 mm) since 1950, after remaining relatively stable for approximately the last 3000 years (Church and White, 2006). However, satellite data collected more recently (from 1993–2009) recorded rates of 0.12 inch \pm 0.015 inch per year (3.3 \pm 0.4 mm), suggesting that SLR may be

accelerating (Ablain *et al.*, 2009). Global sea levels are projected to rise by approximately 23.6 in (60cm) by 2100 (IPCC, 2007) to as much as 39.4 in (1 m) due to recently identified declines in polar ice sheet mass (Pfeffer *et al.*, 2008). However, Washington State sits above an active subduction zone, which may mean that sea-level rise could differ from the global average depending on the activity of the zone (Dalton *et al.*, 2013). Puget Sound lowlands are thought to be more stable in the north, but are tilting downward toward Tacoma in the south. This subsidence may amplify SLR and could effectively double the rate in areas of South Puget Sound, such as Olympia (Craig, 1993). In areas of South Puget Sound, SLR could, among other impacts, alter listed rockfish habitat by contaminating surface and groundwater, or causing shoreline erosion and landslides, which may lead to a loss of tidal and estuarine habitat (Craig, 1993) and alter species distribution (Harley *et al.*, 2006).

More research is needed to further understand rockfish-specific responses and possible adaptations to OA, climate change and sea level rise within the Puget Sound/Georgia Basin. As mentioned previously, we are developing a Recovery Plan for listed rockfishes, and research regarding OA and climate change will likely be a significant component of the draft plan.

Comment 37: One commenter stated that the benthic habitats of Dredge Material Management Program (DMMP) sites in Puget Sound are of low rugosity, but are located near areas of high rugosity, and that these areas may serve as transitory zones for rockfishes. The commenter also noted that the DMMP open-water sites are not highly rugose and that continued disposal of sediment would be unlikely to adversely affect physical and biological features essential to the conservation of listed rockfishes.

Response: In 2010, we completed an ESA section 7 consultation with the U.S. Army Corps of Engineers for the use of eight open-water dredge disposal sites in Puget Sound. In that consultation our analysis found that the benthic habitats of the dredge disposal sites are relatively flat and homogenous but also near more rugose habitats (NMFS, 2010). We agree that the DMMP sites may serve as “transitory” zones for sub-adult and adult listed rockfishes as they move from and to areas of higher rugosity. We note that recent surveys of some of these sites found larval rockfishes in relatively high abundance compared to other sample sites in Puget Sound (Greene and Godersky, 2012). We consider the continued use of the

disposal sites to have the potential for short and transitory effects to the physical and biological features of listed rockfish critical habitat, and will continue to use best available information to assess the effects of the continuous use of these sites in future section 7 consultations.

Comment 38: In reference to our draft Biological Report, one commenter noted that dredge disposal is unlikely to lead to appreciable reductions of dissolved oxygen (DO) levels in the mid or upper portion of the water column after disposal of sediment, nor long-term impacts to the lower portion of the water column. The same commenter noted that sediment plumes with aquatic disposal of dredged materials would be intermittent and short term and unlikely to reduce DO levels.

Response: We agree that most sediment plumes in the water column would likely be intermittent and short term from the discharge of unconsolidated dredge materials. Pertaining to the dispersive sites, we note research that finds that fine-grained materials remain in the water column longer than coarser grained materials, are more widely dispersed, and stay within the water column for extended periods of time (DMMP, 2012). One model-analysis found that 80 percent of sediment parcels remained active in the water column for up to 36 hours following disposal (DMMP, 2012). The results of this analysis indicate that there is potential for habitat changes in the water column while this material disperses.

Economic Impacts of Critical Habitat Designation

Comment 39: Two commenters supported the draft Economic Analysis (NMFS, 2013b), stating that designation will not have economic impacts in part due to most areas of rockfish critical habitat already being designated for other ESA-listed species, and they agreed the incremental impacts method is sound.

Response: We agree.

Comment 40: One commenter stated that it was not clear why the estimated annual administrative cost from critical habitat designation is \$123,000 when ESA section 7(a)(2) consultations are unlikely to result in recommended project modifications. The commenter suggested that these estimated costs should be lower.

Response: Though it is unlikely that many projects will require modifications to protect critical habitat, the estimated administrative costs include the time and resources to conduct the assessment of project effect

and consider adverse modification of listed rockfish critical habitat in section 7 consultations.

Comment 41: One commenter stated that if the designation of critical habitat would cause an “effective ban” on open-water disposal of sediments in Puget Sound it would create a significant economic impact.

Response: As previously mentioned, in 2010 we completed a section 7 consultation with the U.S. Army Corps of Engineers for the use of eight open-water dredge disposal sites in Puget Sound (NMFS, 2010). At the time of the consultation, we estimated the take of individual listed rockfish and also assessed the effects of open-water disposal on their habitat. Some of the habitat that we assessed in the 2010 consultation will now become critical habitat for listed rockfishes. In the 2010 consultation we did not recommend changing the dredge disposal window or contaminant standards for open-water disposal. Based on our previous section 7 consultation that assessed the effects of the program on listed rockfish habitat, the designation of critical habitat would not create an “effective ban” on open-water disposal of sediments nor significantly change the time window to dispose sediments. Therefore we do not anticipate significant economic impacts for this activity above those already considered in our estimated administrative costs (see NMFS, 2014b).

Comment 42: One commenter stated that we should acknowledge that final critical habitat designation will likely increase the complexity and cost of implementing state Hydraulic Project Approval (HPA) and local Shoreline Management Act (SMA) regulatory authority.

Response: Our Economic Analysis (NMFS, 2014b) examined the state of the world with and without the designation of critical habitat for rockfishes. The “without critical habitat” scenario represented the baseline for the analysis, considering protections already afforded rockfish habitat under the Federal listing rule or under other Federal, State, and local regulations. It also included protections afforded to rockfishes resulting from protections for other listed species. These protections are associated with the ESA listing of Puget Sound Chinook salmon and steelhead, Hood Canal summer-run chum salmon, bull trout, eulachon, green sturgeon, and Southern Resident killer whales and the designation of critical habitat for salmonids, killer whales, and green sturgeon where they overlap with rockfish critical habitat. Also included

under the baseline are protections already afforded rockfishes under their ESA listing, including HPA and SMA regulations. The listed rockfish critical habitat designation may provide new information to the State of Washington or a local government about the sensitive ecological nature of a specific area, potentially triggering additional economic impacts under other State or local laws. In cases where these impacts would not have been triggered absent critical habitat designation, they are considered indirect, incremental impacts of the designation and our final Economic Analysis (NMFS, 2014b) estimated these incremental impacts. Yelloweye rockfish, canary rockfish and bocaccio are also listed as “State Candidate” species for the Washington State Species of Concern list (<http://wdfw.wa.gov/conservation/endangered/All/>). Aside from some deepwater habitat in Hood Canal, all areas of rockfish critical habitat are already designated as critical habitat for a combination of the species listed above, and these rockfishes are listed as “State Candidates” under Washington State Law. Therefore, we do not believe that rockfish critical habitat will significantly increase costs associated with administering the HPA program or SMA regulatory authority.

Impacts to National Security

Comment 43: One commenter stated that the Integrated Natural Resource Management Plans (INRMPs) for Department of Defense (DOD) facilities in Puget Sound should provide greater detail on how listed rockfishes will benefit from plan implementation.

Response: We reviewed the INRMPs and found that each contains measures that provide benefits to each listed rockfish DPS (see Appendix C of our section 4(B)(2) report). Examples of the types of beneficial measures include: (1) Implementing actions to protect water quality from land-based infrastructure and vessels; (2) conducting in-water actions during appropriate time periods; and (3) initiating surveys for listed fish.

Comment 44: The Navy requested that our references to “Naval Station Kitsap and associated properties” be changed to “Naval Base Kitsap and associated properties.”

Response: We have made this change within all pertinent documents for final critical habitat designation.

Comment 45: The Navy requested that we exempt Naval Magazine Indian Island property because it has an INRMP that benefits listed rockfishes.

Response: We did propose to exempt Naval Magazine Indian Island in our proposed critical habitat designation,

and we do not include it in this final critical habitat designation because any DOD areas for which we have approved an INRMP (because it provides a conservation benefit to the species) do not meet the definition of critical habitat (ESA Section 4(a)(3)(B)(i)).

Comment 46: The Navy requested clarification on our proposed critical habitat designation within some shallow nearshore areas of Navy security zones. Our supplemental textual descriptions of proposed critical habitat included language that stated “Critical habitat is proposed in a narrow nearshore zone (from the extreme high tide datum down to mean lower low water (MLLW)) within Navy security zone areas not subject to an approved INRMP or associated with Department of Defense easements or rights-of way. . .”. They stated that our definition of this area is confusing, and that a similar definition for Puget Sound Chinook salmon critical habitat has proven to be problematic. The Navy recommended that we clearly separate those areas excluded from critical habitat designation due to national security concerns and those areas proposed for exemption subject to approved INRMPs.

Response: In response to this request we contacted the Navy and verified the facilities and Security Areas that are covered by INRMPs and, therefore, would not be eligible for critical habitat designation. Based on the Navy’s feedback, we have provided additional explanation in Appendix C of our final section 4(b)(2) report (NMFS, 2014c) whether a particular Navy Security Area is also covered by an INRMP, and if any portion of the nearshore is designated as critical habitat for canary rockfish and bocaccio. To summarize, we designate the narrow nearshore zone from extreme high tide down to MLLW at the Admiralty Inlet Naval Restricted Area. After consultation with the Navy, we designated the nearshore (extreme high tide to a depth of 30 m (98ft)) at Carr Inlet Naval Restricted Area. As detailed in NMFS (2014c) none of the rest of the restricted areas or areas covered by an INRMP are designated as critical habitat in any portion of the nearshore.

Comment 47: The Navy requested Naval Base Kitsap (NBK) Bremerton within Sinclair Inlet not be included in the final designation.

Response: The waters within Sinclair Inlet Naval Restricted Area, which encompass NBK Bremerton, were not proposed as critical habitat nor are they designated as such in this final rule. We came to this determination based on an evaluation of the benefits of exclusion to the Navy and the benefits of designation

to rockfish conservation (see Appendix C of our draft 4(b)(2) report).

Comment 48: The Navy requested we include a textual description of the Naval Air Station Whidbey Island Crescent Harbor Restricted Area in the final rule, and stated they would provide this language.

Response: The Navy provided this textual description to us, and we have reviewed it and included it within this final rule.

Comment 49: The Navy requested that Operating Area R-6713 (Navy 3), off the western side of Naval Air Station Whidbey Island, be excluded from critical habitat designation because of impacts to national security. The Navy provided us the rationale for this request by forwarding a copy of their concerns about potential Southern Green Sturgeon Critical Habitat designation they submitted to us in 2009. For green sturgeon, we determined that the benefits to national security of excluding this site outweigh the conservation benefits of designation, and excluded it from the critical habitat designation (74 FR 52300; October 9, 2009). The Navy did not request this area be excluded as Southern Resident killer whale critical habitat, and this area was designated as such in 2006 (70 FR 69054; November 29, 2006).

Response: Under Section 4(b)(2) of the ESA our decision whether to exclude an area is “wholly” discretionary. We updated our evaluation of the benefits of exclusion to the Navy and the benefits of designation to rockfish conservation of this Operating Area based on the additional information provided by the Navy (see Appendix C of our final 4(b)(2) report). As a result, for several reasons we continue to conclude that the benefits to national security of excluding this particular area do not outweigh the benefits to rockfish conservation of designating it. We came to this conclusion after a careful and comprehensive analysis.

This area is critical habitat for Southern Resident killer whales and thus we assessed the extent of Navy consultations for actions in this operating area. We have no consultation records for Navy actions within Navy 3, indicating that use of this area by the Navy is limited or sporadic. According to the Navy, activities in this Operating Area involve surface ship operations, including basic tactical operations, formation maneuvers, engineering trials and testing electronic equipment. We have determined that surface ship operations are not a special management consideration, and such operations conducted by the Navy are unlikely to alter the physical and biological features

of rockfish critical habitat and specifically benthic areas with complex bathymetry. Any consultation for Navy action in this Operating Area would require a section 7 jeopardy analysis for rockfish. As discussed generally in our final Economic Analysis (NMFS 2014b) the adverse modification analysis for the Navy would be an incremental impact from designating a subset of this area as critical habitat. As a result there would be a low administrative burden to the Navy for subsequent section 7 consultations that assess rockfish critical habitat in Navy 3 because their use of this area appears relatively infrequent, actions in this area are unlikely to result in alteration to physical and biological features for listed rockfishes, and any subsequent consultation would undergo a jeopardy analysis as well.

Further, areas designated as critical habitat within Navy 3 for listed rockfishes are centrally located between the San Juan Islands and the mainland to the south, thus providing important spatial structure to listed rockfish populations. In addition, the large size of the Navy 3 area (65.4 sq mi, 169.4 sq km) makes it likely that future Federal activities will occur there that could adversely affect rockfish critical habitat. For instance, a recent analysis shows that this area is potentially affected by the open-water dredge disposal activities (DMMP, 2012). This area also encompasses portions of several popular recreational and commercial fishing areas including Smith Island Bank, McArthur Bank and Partridge Bank and has accumulated several derelict fishing nets. The designation of critical habitat in this area for listed rockfishes will allow future analysis of these activities that may adversely affect listed rockfish critical habitat in an area of high value to the species (NMFS, 2014a).

These specific examples of consultations would occur with other Federal agencies, and thus would not constitute an administrative burden to the Navy, but would potentially bring conservation benefits to important listed rockfish habitats. For these reasons we continue to conclude that the benefits to national security of excluding this particular area do not outweigh the benefits to rockfish conservation of designating it (for a full description of our analysis see Appendix C of our 4(b)(2) report).

Methods and Criteria Used To Identify Specific Areas Eligible for Critical Habitat

In the following sections, we describe the relevant definitions and requirements in the ESA and our

implementing regulations and the key methods and criteria used to prepare this critical habitat designation. Discussion of the specific implementation of each item occurs within the species-specific sections. In accordance with section 4(b)(2) of the ESA and our implementing regulations (50 CFR 424.12), this designation is based on the best scientific information available concerning the species' present and historical range, habitat, and biology, as well as threats to their habitat. In preparing this designation, we reviewed and summarized current information on these species, including recent biological surveys and reports, peer-reviewed literature, NMFS status reviews, public and peer review comments on the proposed critical habitat designation, and the proposed and final rules to list these species. All of the information gathered to create this final rule has been collated and analyzed in three supporting documents: a Biological Report (NMFS, 2014a); an Economic Analysis (NMFS, 2014b); and a Section 4(b)(2) Report (NMFS, 2014c). We used these reports to inform the identification of specific areas as critical habitat.

We followed a five-step process in order to identify these specific areas: (1) Determine the geographical area occupied by the species at the time of listing, (2) identify physical or biological habitat features essential to the conservation of the species, (3) delineate specific areas within the geographical area occupied by the species on which are found the physical or biological features, (4) determine whether the features in a specific area may require special management considerations or protections, and (5) determine whether any unoccupied areas are essential for conservation. As described later, we did not identify any unoccupied areas that are essential for conservation.

Once we identified specific areas, we then considered the economic impact, impact on national security, and any other relevant impacts. The Secretary has the discretion to exclude an area from designation if she determines the benefits of exclusion (that is, avoiding the impact that would result from designation) outweigh the benefits of designation based on the best available scientific and commercial information. In addition, military lands subject to INRMPs pursuant to Section 4(a)(3) the ESA are ineligible for designation if the Secretary certifies that the INRMPs provide benefits to the listed species. Our evaluation and determinations are described in detail in the following sections.

Geographical Area Occupied by the Species

In the status review and final ESA listing for each species, we identified a Puget Sound/Georgia Basin DPS for yelloweye rockfish, canary rockfish, and bocaccio (Drake *et al.*, 2010; 75 FR 22276; April 28, 2010). Our review of the best available data confirmed that yelloweye rockfish, canary rockfish, and bocaccio occupy each of the major biogeographic Basins of the Puget Sound/Georgia Basin (NMFS, 2014a). The range of the DPSs includes portions of Canadian waters; however, we cannot designate areas outside U.S. jurisdiction as critical habitat (50 CFR 424.12(h)). Puget Sound and Georgia Basin make up the southern arm of an inland sea located on the Pacific Coast of North America and connected to the Pacific Ocean by the Strait of Juan de Fuca. The term "Puget Sound proper" refers to the waters east of and including Admiralty Inlet. Puget Sound is a fjord-like estuary covering 2,331.8 square miles (6,039.3 sq km) and has 14 major river systems, and its benthic areas consist of a series of interconnected Basins separated by relatively shallow sills, which are bathymetric shallow areas.

Physical or Biological Features Essential to Conservation

Agency regulations at 50 CFR 424.12(b) interpret the statutory phrase "physical or biological features essential to the conservation of the species." The regulations state that these features include space for individual and population growth and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, and rearing of offspring; and habitats that are protected from disturbance or are representative of the historical geographical and ecological distribution of a species.

Based on the best available scientific information regarding natural history and habitat needs, we developed a list of physical and biological features essential to the conservation of adult and juvenile yelloweye rockfish, canary rockfish, and bocaccio and relevant to determining whether specific areas are consistent with the above regulations and the ESA section (3)(5)(A) definition of "critical habitat." Because larval rockfish are nearly impossible to identify to species visually until they are several months old (Love *et al.*, 2002), there is relatively little known about their life-history on a species-specific level. We do not currently have sufficient information regarding the

habitat requirements of larval yelloweye rockfish, canary rockfish, and bocaccio to determine which features are essential for conservation, and thus are not identifying critical habitat specifically for this life-stage, though we note that larval listed rockfishes very likely use areas designated as critical habitat. The physical or biological features essential to the conservation of yelloweye rockfish, canary rockfish, and bocaccio fall into major categories reflecting key life history phases:

Physical or Biological Features Essential to the Conservation of Adult Canary Rockfish and Bocaccio, and Adult and Juvenile Yelloweye Rockfish

Benthic habitats or sites deeper than 30 m (98ft) that possess or are adjacent to areas of complex bathymetry consisting of rock and or highly rugose habitat are essential to conservation because these features support growth, survival, reproduction, and feeding opportunities by providing the structure for rockfishes to avoid predation, seek food and persist for decades. Several attributes of these sites determine the quality of the habitat and are useful in considering the conservation value of the associated feature, and whether the feature may require special management considerations or protection. These attributes are also relevant in the evaluation of the effects of a proposed action in a section 7 consultation if the specific area containing the site is designated as critical habitat. These attributes include: (1) Quantity, quality, and availability of prey species to support individual growth, survival, reproduction, and feeding opportunities, (2) water quality and sufficient levels of dissolved oxygen to support growth, survival, reproduction, and feeding opportunities, and (3) the type and amount of structure and rugosity that supports feeding opportunities and predator avoidance.

Physical and Biological Features Essential to the Conservation of Juvenile Canary Rockfish and Bocaccio

Juvenile settlement habitats located in the nearshore with substrates such as sand, rock and/or cobble compositions that also support kelp (families Chordaceae, Alariaceae, Lessoniaceae, Costariaceae, and Laminariceae) are essential for conservation because these features enable forage opportunities and refuge from predators and enable behavioral and physiological changes needed for juveniles to occupy deeper adult habitats. Several attributes of these sites determine the quality of the area and are useful in considering the conservation value of the associated

feature and, in determining whether the feature may require special management considerations or protection. These features also are relevant to evaluating the effects of a proposed action in a section 7 consultation if the specific area containing the site is designated as critical habitat. These attributes include: (1) Quantity, quality, and availability of prey species to support individual growth, survival, reproduction, and feeding opportunities; and (2) water quality and sufficient levels of dissolved oxygen to support growth, survival, reproduction, and feeding opportunities.

Specific Areas Within the Geographical Area Occupied by the Species

After determining the geographical area of the Puget Sound/Georgia Basin occupied by adult and juvenile yelloweye rockfish, canary rockfish, and bocaccio, and the physical and biological features essential to their conservation, we next identified the specific areas within the geographical

area occupied by the species that contain the essential features. The U.S. portion of Puget Sound/Georgia Basin that is occupied by yelloweye rockfish, canary rockfish, and bocaccio can be divided into five biogeographic Basins or areas based on the presence and distribution of adult and juvenile rockfish, geographic conditions, and habitat features (Figure 1). These interconnected basins are separated by relatively shallow sills. The configuration of sills and deep basins results in the partial recirculation of water masses in the Puget Sound and the retention of contaminants, sediment, and biota (Strickland, 1983). The sills largely define the boundaries between the Basins and contribute to the generation of relatively fast water currents during portions of the tidal cycle. The sills, in combination with bathymetry, freshwater input, and tidal exchange, influence environmental conditions such as the movement and exchange of biota from one region to the

next, water temperatures and water quality, and they also restrict water exchange (Ebbesmeyer *et al.*, 1984; Burns, 1985; Rice, 2007). In addition, each Basin differs in biological condition; depth profiles and contours; sub-tidal benthic, intertidal habitats; and shoreline composition and condition (Downing, 1983; Ebbesmeyer *et al.*, 1984; Burns, 1985; Rice, 2007; Drake *et al.*, 2010). These areas also meet the definition of specific areas under ESA section (3)(5)(A) because each one contains the physical and biological features essential for conservation for juvenile rearing and/or adult reproduction, sheltering, or feeding for yelloweye rockfish, canary rockfish, and bocaccio. As previously stated, we do not currently have sufficient information regarding the habitat requirements of larval yelloweye rockfish, canary rockfish, and bocaccio to allow us to determine essential features specific to the larval life stage.

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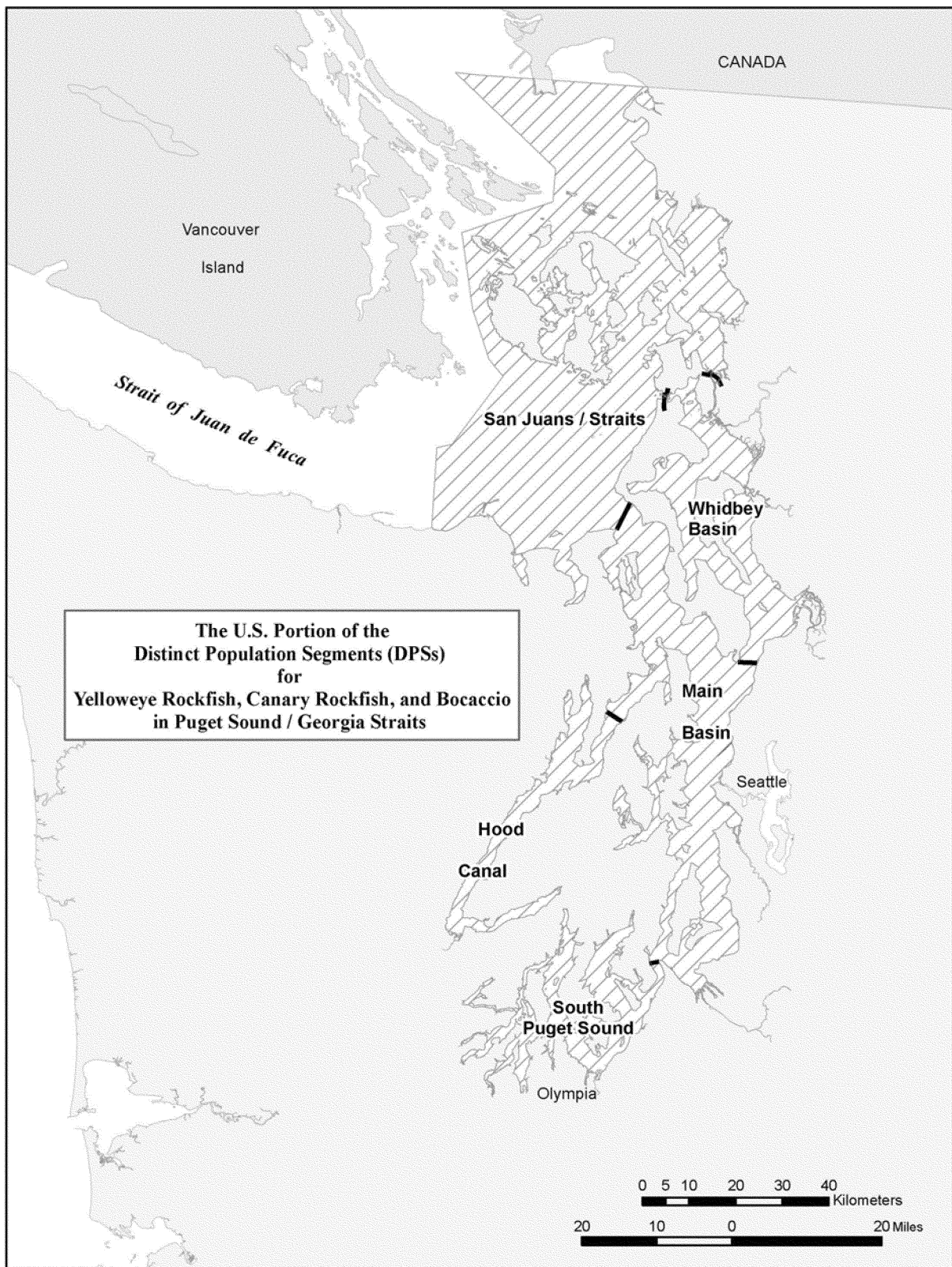


Figure 1. Basins of the U.S. portion rockfish DPSs.

We considered the distribution of the essential features within these areas. We used available geographic data to delineate and map the essential features within each of the specific areas.

Delineating and Mapping Areas of Complex Bathymetry Deeper Than 30 Meters Containing Features Essential to the Conservation of Listed Rockfishes

We modified our proposed critical habitat designation by using newly acquired best available data and GIS tools to better identify areas of essential features that include high rugosity. We also used an updated gridded depth data model created by the Nature Conservancy to identify the 30-meter depth contour. This new bathymetry grid provided a more refined representation of the seafloor than used in our proposed designation in part because it included data from updated surveys conducted in the San Juan area (Greene and Aschoff, 2013). We used ArcGIS, version 10.2, Spatial Analyst (an extension to ArcGIS) and the BTM (Wright *et al.*, 2012) to assist in identifying benthic habitats deeper than 30 m (98 ft) used by yelloweye rockfish, canary rockfish, and bocaccio in Puget Sound that contained the identified essential features. The gridded depth data was the input to the BTM. Its geographic extent encompasses the entire Salish Sea ensuring that the full U.S. portion of the listed rockfish DPSs was covered. The BTM classifies benthic terrain in several categories that include flats, depressions, crests, shelves, and slopes. The BTM does not identify the benthic substrate type. The BTM also generates “rugosity” (terrain complexity or bumpiness) values for the seafloor. In our proposed critical habitat designation we generated rugosity information (used in the BTM version compatible with ArcGIS 9.3), calculated as the ratio of surface area to planar area (Kvitek *et al.*, 2003; Dunn and Halpin, 2009). To develop this final rule, we used the updated rugosity method (available with the BTM under ArcGIS 10.2) which was generated from running the terrain VRM script. The VRM was originally created by Mark Sappington, and was adapted for ArcGIS version 10.1 by the Massachusetts office of Coastal Zone Management (Sappington *et al.*, 2007). The VRM quantifies terrain ruggedness by measuring the dispersion of vectors orthogonal to the terrain surface. Rugosity values were developed using a neighborhood analysis with a 3-grid cell by 3-grid cell neighborhood. The VRM values are both low in flat areas and in steep areas, but values are high in areas that are both steep and rugged. VRM is thus able to differentiate

smooth, steep topography from topography that is irregular and varied in gradient and aspect (Sappington, 2007).

We binned the rugosity values into two groups using the Geometric Interval method (Price, 2011). This method results in groups of classes in a geometric series by each class being multiplied by a constant coefficient to produce the next higher class. We determined the threshold value of high rugosity by using the ArcGIS 10.2 geometrical interval classification method (which is appropriate for the rugosity value data distribution). The geometrical interval method resulted in two classes, and the resultant threshold value for high rugosity was 0.001703 and higher. We refer to benthic areas with rugosity values of 0.001703 or higher as “high rugosity.” All areas of high rugosity (deeper than 30 meters (98 ft)) served as anchor points for critical habitat for each species.

We also designated some habitat between and adjacent to high rugosity by using several generalization geoprocessing tools. The high rugosity polygons were the initial input data, set to the following procedures: (1) The Smooth Polygon Tool was used with the Polynomial Approximation with Exponential Kernel smoothing algorithm with a 600-meter (1,968 ft) tolerance; (2) a 200-meter (656 ft) buffer was run on results from Step 1; (3) the Aggregate Polygons tool was run on results of Step 2 using an aggregation distance of 600 meters; and (4) small resultant non-adult critical habitat polygons that were 0.25 square miles (0.65 sq km) in area or less in waters deeper than 30 meters and having low rugosity were incorporated into surrounding “deepwater” critical habitat. Isolated polygons representing depths deeper than 30 meters that were smaller than 0.25 square miles in area and were entirely surrounded by only nearshore critical habitat were incorporated into nearshore critical habitat making those areas more cohesive.

To assess how well the BTM identified documented rocky areas within the DPSs, we used rocky habitat maps published by Green and Barrie (2011) in the San Juan Island area. We found there were 7.5 square kilometers (2.9 sq mi) of rocky habitat in the San Juan area that was not determined to be high rugosity by the BTM, which is approximately 7 percent of the rocky habitat of this area (Greene and Barrie, 2011). We designated these rocky areas as critical habitat. This mapped rocky habitat was incorporated as critical habitat by either: (1) Incorporating

mapped rock into immediately adjacent high rugosity areas, or (2) a 200-meter buffer was run on those rocky areas.

We found that our GIS methods to identify areas of essential features that include high rugosity in conjunction with the four steps described above, encompassed the vast majority of the documented occurrences with precise spatial data of yelloweye rockfish, canary rockfish and bocaccio within the range of the DPSs. In addition, the spatial area designated as critical habitat for listed rockfish accounts for the movement of individual fish as they grow and move as adults. We further assessed the locations where yelloweye rockfish, canary rockfish and bocaccio had been documented outside of areas of high rugosity. For listed rockfish locations that were outside of the spatial area identified as critical habitat and were reliable and precise, we incorporated these specific locations as critical habitat by creating a 200-meter buffer on the location. These GIS steps resulted in the designation of habitats adjacent to benthic habitat with high rugosity. The designation of these areas next to highly rugose habitats is supported by our understandings of the life history of yelloweye rockfish, canary rockfish and bocaccio, including movement of adult fish and ontogenetic movement.

Delineating and Mapping Settlement Sites Containing Features Essential to the Conservation of Juvenile Canary Rockfish and Bocaccio

In delineating juvenile settlement sites in Puget Sound, we focused on the area contiguous with the shoreline from extreme high water out to a depth no greater than 30 meters relative to MLLW because this area coincides with the maximum depth of the photic zone in Puget Sound and thus, with appropriate substrates that can support the growth of kelp and rearing canary rockfish and bocaccio. To determine the distribution of essential features of nearshore habitats for juvenile canary rockfish and bocaccio, we used the Washington State DNR ShoreZone inventory (Berry, 2001) in combination with the benthic habitat classifications of the BTM related to the locations where moderate and large rivers enter Puget Sound (NMFS, 2014a).

The DNR ShoreZone habitat classifications are available for all of the shoreline within the ranges of the DPSs. We used the habitat characteristics described in the ShoreZone inventory to assist in determining if essential features for juvenile canary rockfish and bocaccio occur along particular nearshore areas. The ShoreZone

inventory was conducted by aerial visual surveys between 1994 and 2000 along all of Washington State's shorelines (Berry *et al.*, 2001). The DNR subdivided beaches into units that are sections of beach with similar geomorphic characteristics. Within each unit, the DNR documented the presence of eelgrass or kelp, among other biological parameters. There are 6,856 shoreline segments in the range of the rockfish DPSs, ranging from 0.02 to 14 kilometers (0.01 to 8.7 mi) in length. The DNR delineated 15 different geomorphic shoreline types. The DNR's mapping of aquatic vegetation had limitations because shoreline segments were observed by aerial surveys during different years and months. Aquatic vegetation growth, including kelp, is variable from month to month and year to year. Some kelp species are annuals, thus surveys that took place during non-growing seasons may have not mapped kelp beds where they actually occur. Non-floating kelp species in particular may have also been underestimated by the DNR survey methods because they were more difficult to document than floating kelp. In particular, all kelp species mapped were usually not visible to their lower depth limit because of poor visibility through the water column. While beds of vegetation may have been visible underwater, often it was not possible to determine what particular type of vegetation was present because of a lack of color characteristics. In addition, because floating kelp occurs in shallow waters, off-shore of the area visible from the aircraft, it was not mapped in many cases. For these reasons, the mapped kelp within the ShoreZone database represents an underestimation of the total amount of kelp along Puget Sound shorelines.

To determine which shorelines contained the essential features for juvenile canary rockfish and bocaccio, we reviewed their geomorphic classifications to see if they possessed "substrates such as sand, rock and/or cobble compositions." In addition, we assessed the relative overlap of mapped kelp in these shoreline types. All but the "Estuary Wetland" and "Mud Flat" type shoreline segments had at least 20 percent of the segment with "continuous" or "sporadic" kelp mapped by DNR. The Estuary Wetland and Mud Flat type segments had very small portions of kelp (1.5 and 2.6 percent, respectively). We found that the Estuary Wetland and Mud Flat type shoreline segments longer than one-half lineal mile in length lack essential features for canary rockfish and bocaccio.

To assess nearshore estuaries and deltas of moderate and large rivers that enter Puget Sound, we used information from Burns (1983) and Teizeen (2012) to determine the location and annual flows of these rivers. These rivers input various volumes of sediment and fresh water into Puget Sound (Downing, 1983; Burns, 1985; Czuba *et al.*, 2011) and profoundly influence local benthic habitat characteristics, salinity levels, and local biota. The nearshore areas adjacent to moderate-to-large river deltas are characterized by the input of fresh water and fine sediments that create relatively flat habitats (termed "shelves" by the BTM) that do not support the growth of kelp (NMFS, 2014a). In addition, the net outward flow of these deltas may prevent post-settlement juvenile canary rockfish or bocaccio from readily using these habitats. For these reasons we found that these nearshore areas do not contain the essential features of rearing sites for canary rockfish or bocaccio (juvenile yelloweye rockfish most commonly occupy waters deeper than the nearshore).

The DNR ShoreZone survey did not delineate the geomorphic extent of shoreline segments associated with estuaries and deltas. Thus we determined the geographical extent of these estuaries and shelves from the BTM "shelf" seafloor designation associated with the particular river because it indicates the geomorphic extension of the tidal and sub-tidal delta where fresh water enters Puget Sound. Not all of the shorelines associated with estuaries and deltas were labeled as "estuary wetland" and "mud flat" by DNR, thus we delineated juvenile settlement sites located in the nearshore at the border of these deltas at the geomorphic terminus of the delta at the 30 m (98 ft) contour and/or at the shoreline segment mapped with kelp by the DNR. By doing this, we did not include some of the other ShoreZone geomorphic shoreline types in the critical habitat designation because available information did not support the presence of essential features at some specific areas adjacent to moderate to large rivers (see NMFS, 2014a).

Special Management Considerations or Protection

An occupied area cannot be designated as critical habitat unless it contains physical or biological features that "may require special management considerations or protection." Agency regulations at 50 CFR 424.02(j) define "special management considerations or protection" to mean "any methods or procedures useful in protecting physical

and biological features of the environment for the conservation of listed species." Many forms of human activities have the potential to affect the essential features of listed rockfish species: (1) Nearshore development and in-water construction (e.g., beach armoring, pier construction, jetty or harbor construction, pile driving construction, residential and commercial construction); (2) dredging and disposal of dredged material; (3) pollution and runoff; (4) underwater construction and operation of alternative energy hydrokinetic projects (tidal or wave energy projects) and cable laying; (5) kelp harvest; (6) fisheries; (7) non-indigenous species introduction and management; (8) artificial habitats; (9) research activities; (10) aquaculture, and; (11) activities that lead to global climate change and ocean acidification. All of these activities may have an effect on one or more physical or biological features via their potential alteration of one or more of the following: adult habitats, food resources, juvenile settlement habitat, and water quality. Further detail regarding the biological and ecological effect of these species management considerations is found in the final Biological Report (NMFS, 2014a).

Descriptions of Essential Features and Special Management Considerations in each Specific Area

We describe the five Basins (the specific areas) of the Puget Sound below and summarize their biological condition and attributes; full details are found in the final biological report supporting this designation (NMFS, 2014a). Each Basin has different levels of human impacts related to the sensitivity of the local environment, and degree and type of human-derived impacts. We have also included examples of some of the activities that occur within these Basins that affect the essential features such that they may require special management considerations or protection.

The San Juan/Strait of Juan de Fuca Basin—This Basin is the northwestern boundary of the U.S. portion of the DPSs. The Basin is delimited to the north by the Canadian border and includes Bellingham Bay, to the west by the entrance to the Strait of Juan de Fuca, to the south by the Olympic Peninsula and Admiralty Inlet, and to the east by Whidbey Island and the mainland between Anacortes and Blaine, Washington. The predominant feature of this Basin is the Strait of Juan de Fuca, which is 99.4 mi (160 km) long and varies from 13.7 mi (22 km) wide at its western end to over 24.9 mi (40

km) wide at its eastern end (Thomson, 1994). Drake *et al.* (2010) considered the western boundary of the DPSs as the Victoria Sill because it is hypothesized to control larval dispersal for rockfishes (and other biota) of the region. Water temperatures are lower and more similar to coastal marine waters than to Puget Sound proper, and circulation in the strait consists of a seaward surface flow of diluted seawater (>30.0 practical salinity units [psu]) in the upper layer and an inshore flow of saline oceanic water (>33.0 psu) at depth (Drake *et al.*, 2010). Water exchange in this Basin has not been determined because, unlike the rest of the Basins of the DPSs, it is more oceanic in character and water circulation is not nearly as constrained by geography and sills as it is in the other Basins.

The San Juan/Straits of Juan de Fuca Basin has the most rocky shoreline and benthic habitats of the U.S. portion of the DPSs. Most of the Basin's numerous islands have rocky shorelines with extensive, submerged aquatic vegetation and floating kelp beds necessary for juvenile canary rockfish and bocaccio settlement sites.

This Basin also contains abundant sites deeper than 30 meters that possess or are adjacent to areas of complex bathymetry. Approximately 93 percent of the rocky benthic habitats of the U.S. portion of the range of all three DPSs are in this Basin (Palsson *et al.*, 2009). Plate tectonic processes and glacial scouring/deposition have produced a complex of fjords, grooved and polished bedrock outcrops, and erratic boulders and moraines along the seafloor of the San Juan Archipelago (Greene, 2012). Banks of till and glacial advance outwash deposits have also formed and contribute to the variety of relief and habitat within the Basin. These processes have contributed to the development of benthic areas with complex bathymetry.

Yelloweye rockfish, canary rockfish, and bocaccio have been documented in the San Juan Archipelago, in addition to the southern portion of this Basin along the Strait of Juan de Fuca (Washington, 1977; Moulton and Miller, 1987; Pacunski, 2013). The southern portion of this Basin has several pinnacles that include Hein, Eastern, Middle, MacArthur, Partridge, and Coyote Banks. Yelloweye rockfish were once commonly caught by anglers along these areas, particularly Middle Bank (Olander, 1991).

As described in more detail in the final Biological Report (NMFS, 2014a), there are several activities that occur in this Basin that affect the essential features such that they may require

special management considerations. Commercial and recreational fisheries occur here, as well as scientific research. The highest concentration of derelict fishing nets within the range of the DPSs remain here, including over 199 nets in waters deeper than 100 ft (30.5 m) (NRC, 2014), and an estimated 241 nets in waters shallower than 100 ft (30.5 m) (NRC, 2014). Because this Basin has the most kelp within the range of the DPSs, commercial harvest of kelp could be proposed for the San Juan Islands area. The Ports of Bellingham and Anacortes are located in this Basin, and numerous dredging and dredge disposal projects and nearshore development, such as new docks, piers, and bulkheads occur in this Basin. These development actions have the potential to alter juvenile settlement sites of canary rockfish and bocaccio. Two open-water dredge disposal sites are located in the Basin, one in Rosario Strait and the other northwest of Port Townsend. These are termed dispersive sites because they have higher current velocities; thus, dredged material does not accumulate at the disposal site and settles on benthic environments over a broad area (Army Corps of Engineers, 2010). Sediment disposal activities in this specific area may temporarily alter water quality (dissolved oxygen levels) and feeding opportunities (the ability of juvenile rockfish to seek out prey). There are several areas with contaminated sediments along the eastern portion of this Basin, particularly in Bellingham Bay and Guemes Channel near Anacortes.

Whidbey Basin—The Whidbey Basin includes the marine waters east of Whidbey Island and is delimited to the south by a line between Possession Point on Whidbey Island and Meadowdale, south of Mukilteo. The northern boundary is Deception Pass at the northern tip of Whidbey Island. The Skagit, Snohomish, and Stillaguamish Rivers flow into this Basin and contribute the largest influx of freshwater inflow to Puget Sound (Burns, 1985). Water retention is approximately 5.4 months due to the geography and sills at Deception Pass (Ebbesmeyer *et al.*, 1984).

Most of the nearshore of the Whidbey Basin consists of bluff-backed beaches with unconsolidated materials ranging from mud and sand to mixes of gravels and cobbles (McBride, 2006). Some of these nearshore areas support the growth of kelp. Some of the northern part of this Basin is relatively shallow with moderately flat bathymetry near the Skagit, Stillaguamish and Snohomish River deltas and does not support kelp growth because it lacks

suitable areas for holdfast attachment, such as rock and cobble.

Benthic areas in this Basin contain sites deeper than 30 meters that possess or are adjacent to areas of complex bathymetry. The southern portion of the Basin has more complex bathymetry compared to the north, with deeper waters adjacent to Whidbey Island, southern Camano Island, and near the City of Mukilteo.

Yelloweye rockfish, canary rockfish, and bocaccio have been documented in the Whidbey Basin, with most occurrences within the southern portion near south Camano Island, Hat (Gedney) Island, and offshore of the City of Mukilteo. It is not known if the southern portion of the Whidbey Basin has more attractive rockfish habitat compared to the northern portion, or if most documented occurrences are a reflection of uneven sampling effort over the years.

As described in more detail in the biological report, there are several activities that occur in this Basin that affect the essential features such that they may require special management considerations. Activities include commercial and recreational fisheries, scientific research, dredging projects and dredge disposal operations, nearshore development projects, aquaculture and potential tidal energy projects. An estimated 3 derelict nets remain in waters deeper than 100 ft (30.5 m) and 3 nets in deeper waters in this Basin (NRC, 2014). A planned tidal energy site is located within the Deception Pass area, at the northern tip of Whidbey Island. Pollution and runoff are also concerns in this Basin, mostly near the Port Gardner area. There are several areas with contaminated sediments along the eastern portion of this Basin, particularly near the Cities of Mukilteo and Everett.

Main Basin—The 62.1 mi (100 km) long Main Basin is delimited to the north by a line between Point Wilson near Port Townsend and Partridge Point on Whidbey Island, to the south by Tacoma Narrows, and to the east by a line between Possession Point on Whidbey Island and Meadow Point. The sill at the border of Admiralty Inlet and the eastern Straits of Juan de Fuca regulates water exchange of Puget Sound (Burns, 1985). The Main Basin is the largest Basin, holding 60 percent of the water in Puget Sound proper. Water retention is estimated to be one month due to the sills at Admiralty Inlet and Deception Pass (Ebbesmeyer *et al.*, 1984).

Approximately 33 percent (439.3 mi (707 km)) of Puget Sound's shoreline occurs within this Basin and nearshore

habitats consist of bluff-backed beaches with unconsolidated materials ranging from mud and sand to mixes of gravels and cobbles (Drake *et al.*, 2010). Some of these nearshore areas support the growth of kelp. Subtidal surface sediments in Admiralty Inlet tend to consist largely of sand and gravel, whereas sediments just south of the inlet and southwest of Whidbey Island are primarily sand. Areas deeper than 30 meters in the Main Basin have varying amounts of sites that possess or are adjacent to areas of complex bathymetry. Sediments in the deeper areas of the central portion of the Main Basin generally consist of mud or sandy mud (Bailey *et al.*, 1998) and are generally not complex. Possession Point is centrally located within this Basin at the southern end of Whidbey Island, and has relatively steep eastern, southern, and western edges and also has some rocky substrates (Squire and Smith, 1977). There are benthic areas deeper than 98 ft (30 m) along Possession Point, Admiralty Inlet and the rims of Puget Sound beyond the nearshore that feature complex bathymetry, with slopes and areas of high rugosity.

Yelloweye rockfish, canary rockfish, and bocaccio have been documented at Possession Point, near the port of Kingston and Apple Cove, and along much of the eastern shoreline of this Basin (Washington, 1977; Moulton and Miller, 1987).

As described in more detail in the biological report, there are several activities that occur in this Basin that affect the essential features such that they may require special management considerations. Activities include commercial and recreational fisheries, scientific research, dredging projects and dredge disposal operations, nearshore development projects, aquaculture and planned tidal energy projects. An estimated 20 derelict nets in waters shallower than 100 ft (30.5 m), and one in deeper waters remain in this Basin (NRC, 2014). A planned tidal energy site is located within the Admiralty Inlet area off Whidbey Island. Pollution and runoff are also concerns in this Basin because of extensive amounts of impervious surface located on its eastern side. Two open-water dredge disposal sites are located in the Basin, one located in Elliot Bay and the other in Commencement Bay. These are non-dispersive disposal sites, which are areas where currents are slow enough that dredged material is deposited on the disposal target area rather than dispersing broadly with prevailing currents (Army Corps of Engineers, 2010). An estimated 36 percent of the

shoreline in this area has been modified by human activities (Drake *et al.*, 2010) and bulkhead/pier repair projects and new docks/piers are proposed regularly in this Basin. There are several areas with contaminated sediments in this Basin, particularly in Elliot Bay, Sinclair Inlet, and Commencement Bay.

South Puget Sound—This Basin includes all waterways south of Tacoma Narrows, and is characterized by numerous islands and shallow (generally <65 ft (20 m)) inlets with extensive shoreline areas. The sill at Tacoma Narrows restricts water exchange between the South Puget Sound and the Main Basin and water retention is an estimated 1.9 months (Ebbesmeyer *et al.*, 1984). This restricted water exchange influences environmental characteristics of the South Puget Sound such as nutrient levels and dissolved oxygen, and perhaps its biotic communities (Ebbesmeyer *et al.*, 1984; Rice, 2007).

Wide assortments of sediments are found in the nearshore and intertidal areas of this Basin (Bailey *et al.*, 1998). The most common sediments and the percent of the intertidal area they cover (with 95 percent confidence limits) are: mud, 38.3 ± 29.3 percent; sand, 21.7 ± 23.9 percent; mixed fine, 22.9 ± 16.1 percent; and gravel, 11.1 ± 4.9 percent. Subtidal areas have a similar diversity of surface sediments, with shallower areas consisting of mixtures of mud and sand and deeper areas consisting of mud (Puget Sound Water Quality Authority, 1987). The southern inlets of this Basin include Oakland Bay, Totten Inlet, Bud Inlet and Eld Inlet, in addition to the Nisqually River delta. These inlets have relatively muddy habitats that do not support essential nearshore features such as holdfasts for kelp, and rock and cobble areas for rearing juvenile canary rockfish and bocaccio. Despite the prevalence of muddy and sandy substrate in the southern portion of this Basin, some of these nearshore areas support the growth of kelp and therefore contain juvenile settlement sites.

With a mean depth of 121 ft (37 m), this Basin is the shallowest of the five Basins (Burns, 1985). Benthic areas deeper than 98 ft (30 m) occur in portions of the Tacoma Narrows and Dana Passage and around the rims of the Basin. Sediments in Tacoma Narrows and Dana Passage consist primarily of gravel and sand. The rims of South Puget Sound beyond the nearshore feature complex bathymetry, with slopes and areas of high rugosity.

Yelloweye rockfish, canary rockfish, and bocaccio have been documented within the South Puget Sound (NMFS, 2014a). Canary rockfish may have been

historically most abundant in the South Puget Sound (Drake *et al.*, 2010).

As described in more detail in the biological report, there are several activities that occur in this Basin that affect the essential features such that they may require special management considerations. Activities include commercial and recreational fisheries, scientific research, dredging and dredge disposal, nearshore development, pollution and runoff, aquaculture operations, and potential tidal energy projects. An estimated 7 derelict nets in waters shallower than 100 ft (30.5 m) remain in this Basin (Northwest Straits Initiative, 2011). A non-dispersive dredge disposal site is located off Anderson/Ketron Island (Army Corps of Engineers, 2010). A potential tidal energy site is located in the Tacoma Narrows area. Important point sources of waste include sewage treatment facilities, and about 5 percent of the nutrients (as inorganic nitrogen) entering greater Puget Sound enter this Basin through nonpoint sources (Embrey and Inkpen, 1998). An estimated 34 percent of the shoreline in this area has been modified by human activities (Drake *et al.*, 2010), and bulkhead/pier repair projects and new docks/piers are proposed regularly in this Basin. The major urban areas, and thus more pollution and runoff into the South Puget Sound, are found in the western portions of Pierce County. Other urban centers in Southern Puget Sound include Olympia and Shelton. There are several areas with contaminated sediments in this Basin in Carr Inlet and near Olympia.

Hood Canal—Hood Canal branches off the northwest part of the Main Basin near Admiralty Inlet and is the smallest of the greater Puget Sound Basins, being 55.9 mi (90 km) long and 0.6 to 1.2 mi (1 to 2 km) wide (Drake *et al.*, 2010). Water retention is estimated at 9.3 months; exchange in Hood Canal is regulated by a 164-foot (50-meter) deep sill near its entrance that limits the transport of deep marine waters in and out of Hood Canal (Ebbesmeyer *et al.*, 1984; Burns, 1985). The major components of this Basin consist of the Hood Canal entrance, Dabob Bay, the central Basin, and the Great Bend at the southern end. A combination of relatively little freshwater inflow, the sill at Admiralty Inlet, and bathymetry lead to relatively slow currents; thus, water residence time within Hood Canal is the longest of the biogeographic Basins, with net surface flow generally northward (Ebbesmeyer *et al.*, 1984).

The intertidal and nearshore zone consists mostly of mud (53.4 ± 89.3 percent of the intertidal area), with

similar amounts of mixed fine sediment and sand (18.0 ± 18.5 percent and 16.7 ± 13.7 percent, respectively) (Bailey *et al.*, 1998). Some of the nearshore areas of Hood Canal have cobble and gravel substrates intermixed with sand that support the growth of kelp. Surface sediments in the subtidal areas also consist primarily of mud and cobbles (Puget Sound Water Quality Authority, 1987). The shallow areas of the Great Bend, Dabob Bay, and the Hamma Hamma, Quilcene, Duckabusch, Dosewallips, Tahuya and Skokomish River deltas feature relatively muddy habitats that lack holdfasts for kelp, such as rock and cobble areas, and thus do not support kelp growth. Such areas thus lack the essential feature of juvenile settlement sites for juvenile canary rockfish and bocaccio.

Benthic areas deeper than 98 ft (30 m) occur along the rim of nearly all of Hood Canal, and these areas feature complex bathymetry, with slopes and areas of high rugosity.

Bocaccio have been documented in Hood Canal (NMFS, 2014a). Yelloweye and canary rockfish have also been documented at several locations and have been caught in relatively low numbers for the past several years (WDFW, 2011).

As described in more detail in the biological report, there are several activities that occur in this Basin that affect the essential features such that they may require special management considerations. Activities in Hood Canal include commercial and recreational fisheries, scientific research, nearshore development, non-indigenous species management, aquaculture, and pollution and runoff. An estimated three derelict nets in waters shallower than 100 ft (30.5 m) and two in deeper waters remain in this Basin (NRC, 2014). The unique bathymetry and low water exchange have led to episodic periods of low dissolved oxygen (Newton *et al.*, 2007), though the relative role of nutrient input from humans in exacerbating these periods of hypoxia is in doubt (Cope and Roberts, 2012). Dissolved oxygen levels have decreased to levels that cause behavioral changes and kill some rockfish (i.e., below 1.0 mg/L (1 ppm)) (Palsen *et al.*, 2008). An estimated 34 percent of the shoreline in this area has been modified by human activities (Drake *et al.*, 2010), and bulkhead/pier repairs and new docks/piers are regularly proposed in this Basin. The non-indigenous tunicate (*Ciona savignyi*) has been documented at 86 percent of sites surveyed in Hood Canal (Drake *et al.*, 2010), and may impact benthic habitat function that

includes rearing and settlement habitat for rockfish.

Depicting Critical Habitat With Maps

As previously described, we updated our methods to determine the final critical habitat designation by using newly acquired best available bathymetry data and GIS tools. We used ArcGIS, version 10.2 and updated 30-meter bathymetry data provided to us by the Nature Conservancy. We used the new BTM within ArcGIS 10.2 (Wright *et al.*, 2012). We used available geographic data to identify the locations of benthic sites with or adjacent to complex bathymetry and shoreline sites with sand, rock and/or cobble compositions that also support kelp, as described in more detail in the Biological Report (NMFS, 2014a). Once we identified these sites, we aggregated sites located in close proximity through GIS methods described in NMFS (2014a), consistent with the regulatory guidance regarding designation of an inclusive area for habitats in close proximity (50 CFR 424.12(d)).

Consistent with current agency regulations we refined the designation and provide a critical habitat map that clearly delineates where the essential features are found within the specific areas and, consistent with our proposed designation, are only designating those areas that are mapped. Current agency regulations state that instead of designating critical habitat using lines on a map, we may show critical habitat on a map, with additional information discussed in the preamble of the rulemaking and in agency records (50 CFR 424.12(c)), rather than requiring long textual description in the Code of Federal Regulations (CFR). In adopting this regulation, we stated in response to comments:

[I]n instances where there are areas within a bigger area that do not contain the physical and biological features necessary for the conservation of the species, the Services would have the option of drawing the map to reflect only those parts of the area that do contain those features (77 FR 25611, May 1, 2012).

The maps we developed for the present designation conform to this new regulation. In addition, in agency records, and available on our Web site, we provide the GIS plot points used to create these maps, so interested persons may determine whether any place of interest is within critical habitat boundaries (<http://www.wcr.noaa.gov>).

Unoccupied Areas

Section 3(5)(A)(ii) of the ESA authorizes the designation of “specific areas outside the geographical area

occupied at the time [the species] is listed” if these areas are essential for the conservation of the species. Regulations at 50 CFR 424.12(e) emphasize that the agency “shall designate as critical habitat areas outside the geographical area presently occupied by a species only when a designation limited to its present range would be inadequate to ensure the conservation of the species.” We conducted a review of the documented occurrences of each listed rockfish species in the five biogeographic Basins of Puget Sound (NMFS, 2014a). We found that each of the Basins is currently occupied by listed rockfish and our biological review did not identify any unoccupied areas that are essential to conservation and thus have not identified any unoccupied areas as candidates for critical habitat designation (NMFS, 2014a).

Section 3(5)(C) of the ESA provides that “[e]xcept in those circumstances determined by the Secretary, critical habitat shall not include the entire geographical area which can be occupied by the threatened or endangered species.” In this case we are proposing to designate all the specific areas that possess essential features that can be mapped (such as complex bathymetry in waters deeper than 30 meters, and nearshore areas such as sand, rock and/or cobble compositions that also support kelp) and as described above, we are only designating those portions of the specific areas that actually contain the essential features. We acknowledge that some listed rockfishes have been documented to occur outside of the mapped areas that we designate as critical habitat (NMFS, 2014a) and that larval listed rockfishes could occur throughout the specific areas. Therefore, although each specific area contains designated critical habitat, we conclude that the designation does not constitute “the entire geographical area which can be occupied” by the listed rockfish species.

Identifying Military Lands Ineligible for Designation

Section 4(a)(3) of the ESA precludes the Secretary from designating military lands as critical habitat if those lands are subject to an INRMP under the Sikes Act that the Secretary certifies in writing benefits the listed species. The Navy has not determined the extent of marine waters covered by INRMPs, nor has it set forth a process or timeline to determine this. In considering the benefits of the INRMPs for rockfishes we have determined that they may influence habitat of the nearshore (78 FR 47635; August 6, 2013). These areas are contiguous with the shoreline from

the line of extreme high water out to a depth no greater than 30 meters (98 ft) relative to MLLW (NMFS, 2014a). This zone includes the photic zone (upper layer of a water body delineated by the depth at which enough sunlight can penetrate to allow photosynthesis) which can be readily affected by actions occurring in intertidal waters or adjacent land. Prior to the proposed rule we consulted with the DOD and determined that there are several installations with INRMPs which overlap with marine habitats occupied by listed rockfishes: (1) Joint Base Lewis-McChord; (2) Manchester Fuel Department, (3) Naval Air Station Whidbey Island, (4) Naval Station Everett, and (5) Naval Station Kitsap and associated properties. After the proposed rule (78 FR 47635; August 6, 2013) published, the Navy clarified that Hood Canal and Dabob Bay Naval Non-Explosive Torpedo Testing Area and Dabob Bay, Whitney Point Naval Restricted Area are covered by the

INRMP for Naval Station Kitsap. The Navy also clarified that the two Naval Restricted Areas in the Strait of Juan de Fuca, Eastern End; off the Westerly Shore of Whidbey Island, the Port Townsend, Indian Island, Walan Point Naval Restricted Area, Port Orchard Naval Restricted Area and the Puget Sound, Manchester Fuel Depot, Naval Restricted Area are also covered by an INRMP.

We found that Naval Station Everett is covered by an INRMP that would benefit listed rockfishes, but we also found the nearshore of this area does not overlap with essential features for listed rockfishes and we are not designating it as critical habitat. We identified habitat meeting the statutory definition of critical habitat at all of the other installations and reviewed the INRMPs, as well as other information available, regarding the management of these military lands. Our review indicates that each of these INRMPs addresses listed rockfish habitat, and all

contain measures that provide benefits to the listed rockfish DPSs. Examples of the types of benefits include actions that improve shoreline conditions, control erosion and water quality, prevent or ensure prompt response to chemical and oil spills, and monitor listed species and their habitats. As a result, we conclude that the areas identified within INRMPs are not eligible for critical habitat designation (see Appendix C of NMFS, 2014c).

Summary of Areas Meeting the Definition for Critical Habitat Designation

We have determined that approximately 644.7 square miles (1,669.8 sq km) of nearshore habitat for juvenile canary rockfish and bocaccio, and 438.5 square miles (1,135.7 sq km) of deepwater habitat for yelloweye rockfish, canary rockfish, and bocaccio meet the definition of critical habitat (Table 1).

TABLE 1—PHYSICAL AND BIOLOGICAL FEATURES AND MANAGEMENT CONSIDERATIONS FOR YELLOWEYE ROCKFISH, CANARY ROCKFISH AND BOCACCIO IN AREAS MEETING THE DEFINITION OF CRITICAL HABITAT, PRIOR TO EXCLUSIONS

DPS basin	Nearshore sq mi. (for juvenile canary and bocaccio only)	Deepwater sq mi. (for adult and juvenile yelloweye rockfish, adult canary rockfish, and adult bocaccio)	Physical or biological features		Activities
San Juan/Strait of Juan de Fuca.	349.4	203.6	Deepwater sites <30 meters) that support growth, survival, reproduction and feeding opportunities.	Nearshore juvenile rearing sites with sand, rock and/or cobbles to support forage and refuge.	1, 2, 3, 6, 9, 10, 11.
Whidbey Basin	52.2	32.2			1, 2, 3, 4, 6, 9, 10, 11.
Main Basin	147.4	129.2			1, 2, 3, 4, 6, 7, 9, 10, 11.
South Puget Sound	75.3	27.1			1, 2, 3, 4, 6, 7, 9, 10, 11.
Hood Canal	20.4	46.4			1, 2, 3, 6, 7, 9, 10, 11.

Management Considerations Codes: (1) Nearshore development and in-water construction (e.g., beach armoring, pier construction, jetty or harbor construction, pile driving construction, residential and commercial construction); (2) dredging and disposal of dredged material; (3) pollution and runoff; (4) underwater construction and operation of alternative energy hydrokinetic projects (tidal or wave energy projects) and cable laying; (5) kelp harvest; (6) fisheries; (7) non-indigenous species introduction and management; (8) artificial habitats; (9) research; (10) aquaculture; and (11) activities that lead to global climate change and ocean acidification.

Commercial kelp harvest does not occur presently, but would probably be concentrated in the San Juan/Georgia Basin. Artificial habitats could be proposed to be placed in each of the Basins. Non-indigenous species introduction and management could occur in each Basin.

Application of ESA Section 4(b)(2)

The foregoing discussion describes those areas that are eligible for designation as critical habitat—the specific areas that fall within the ESA section 3(5)(A) definition of critical habitat, not including lands owned or controlled by the DOD, or designated for its use, that are covered by an INRMP

that the Secretary has determined in writing provides a benefit to the species. Specific areas eligible for designation are not automatically designated as critical habitat. As described above, Section 4(b)(2) of the ESA requires that the Secretary first consider the economic impact, impact on national security, and any other relevant impact. The Secretary has the discretion to exclude an area from designation if she determines the benefits of exclusion (that is, avoiding the impact that would result from designation) outweigh the benefits of designation, based on the best available scientific and commercial information. The Secretary may not exclude an area from designation if

exclusion will result in the extinction of the species. Because the authority to exclude is wholly discretionary, exclusion is not required for any areas (H.R. No. 95–1625, at 16–17 1978; M–37016, “The Secretary’s Authority to Exclude Areas from a Critical Habitat Designation under Section 4(b)(2) of the Endangered Species Act” (Oct. 3, 2008) (DOI, 2008; 78 FR 53058, August 18, 2013).

The first step in conducting an ESA section 4(b)(2) analysis is to identify the “particular areas” to be analyzed. Section 3(5)(A) of the ESA defines critical habitat as “specific areas,” while section 4(b)(2) of the ESA requires the agency to consider certain factors before designating any “particular area.” Depending on the biology of the species, the characteristics of its habitat, and the nature of the impacts of designation, “specific” areas might be different from, or the same as, “particular” areas. For this designation, we identified the “specific” areas as (1) The San Juan/Strait of Juan de Fuca Basin, (2) Main Basin, (3) Whidbey Basin, (4) South Puget Sound, and (5) Hood Canal. For our economic impact analysis we defined the “particular” areas as equivalent to the “specific” areas. This approach allowed us to most effectively consider the conservation value of the different areas when balancing conservation benefits of designation against economic benefits of exclusion. However, to assess impacts of designation on national security and Indian lands, we instead used a delineation of “particular” areas based on ownership or control of the area. These “particular” areas consisted of marine areas that overlap with designated military areas and Indian lands. This approach allowed us to consider impacts and benefits associated with management by the military or land ownership and management by Indian tribes.

Identify and Determine the Impacts of Designation

Section 4(b)(2) of the ESA provides that the Secretary shall consider “the economic impact, impact on national security, and any other relevant impact of specifying any particular area as critical habitat.” The primary impact of a critical habitat designation stems from the requirement under section 7(a)(2) of the ESA that Federal agencies ensure their actions are not likely to result in the destruction or adverse modification of critical habitat. Determining this impact is complicated by the fact that section 7(a)(2) contains the overlapping requirement that Federal agencies must ensure their actions are not likely to

jeopardize the species’ continued existence. The true impact of designation is the extent to which Federal agencies modify their actions to ensure their actions are not likely to destroy or adversely modify the critical habitat of the species, beyond any modifications they would make because of listing and the jeopardy requirement for the species. Additional impacts of designation include state and local protections that may be triggered as a result of the designation.

In determining the impacts of designation, we assessed the incremental change in Federal agency actions as a result of critical habitat designation and the adverse modification prohibition, beyond the changes predicted to occur as a result of listing and the jeopardy provision. In August 2013 the USFWS and NMFS published a final rule to amend our joint regulations at 50 CFR 424.19 to make clear that in considering impacts of designation as required by Section 4(b)(2) we would consider the incremental impacts (78 FR 53058; August 24, 2013). This approach is in contrast to our 2005 critical habitat designations for salmon and steelhead (70 FR 52630; September 2, 2005) where we considered the “coextensive” impact of designation. The consideration of co-extensive impacts was in accordance with a Tenth Circuit Court decision (*New Mexico Cattle Growers Association v. U.S. Fish and Wildlife Service*, 248 F.3d 1277 (10th Cir. 2001)). More recently, several courts (including the 9th Circuit Court of Appeals) have approved an approach that considers the incremental impact of designation. The **Federal Register** notice (77 FR 5103; August 24, 2012) announcing the proposed policy on considering impacts of designation describes and discusses these court cases: *Arizona Cattlegrowers’ Ass’n v. Salazar*, 606 F.3d 1160, 1172–74 (9th Cir. 2010), cert. denied, 131 S. Ct. 1471, 179 L. Ed. 2d 300 (2011); *Homebuilders Ass’n v. FWS*, 616 F.3d 983, 991093j (9th Cir. 2010) cert. denied, 131 S. Ct. 1475, 179 L. Ed. 2d 301 (2011). The notice also discusses a Department of Interior Solicitor’s memo (M–3706 The Secretary’s Authority to Exclude Areas from Critical Habitat Designation Under 4(b)(2) of the Endangered Species Act (Oct. 3, 2008) (DOI, 2008)). In more recent critical habitat designations, both NMFS and the USFWS have considered the incremental impact of critical habitat designation (for example, NMFS’ designation of critical habitat for the Southern DPS of green sturgeon (74 FR 52300; October 9, 2009) and the

Southern DPS of Pacific eulachon (76 FR 65324; October 20, 2011), and the USFWS’ designation of critical habitat for the Oregon chub (75 FR 11031; March 10, 2010)).

Consistent with our new regulations (78 FR 53058; August 24, 2013), the more recent court cases, and more recent agency practice, we estimated the incremental impacts of designation, beyond the impacts that would result from the listing and jeopardy provision. In addition, because these designations almost completely overlap our previous salmonid, killer whale and green sturgeon critical habitat designations in Puget Sound, and the essential features defined for those species in previous designations are similar to those for listed rockfishes (NMFS, 2014a), we estimated only the incremental impacts of designation beyond the impacts already imposed by those prior designations.

To determine the impact of designation, we examined what the state of the world would be with and without the designation of critical habitat for listed rockfishes. The “without critical habitat” scenario represents the baseline for the analysis. It includes process requirements and habitat protections already afforded listed rockfishes under their Federal listing or under other Federal, state, and local regulations. Such regulations include protections afforded listed rockfish habitat from other co-occurring ESA listings and critical habitat designations, such as those for Pacific salmon and steelhead (70 FR 52630; September 2, 2005), North American green sturgeon (74 FR 52300; October 9, 2009), Southern Resident killer whales (71 FR 69054; November 29, 2006), and bull trout (75 FR 63898; October 18, 2010) (see the Final Economic Analysis for listed rockfish (NMFS, 2014a) for examples of protections for other species that would benefit listed rockfishes). The “with critical habitat” scenario describes the incremental impacts associated specifically with the designation of critical habitat for listed rockfishes. The primary impacts of critical habitat designation we found were: (1) The economic costs associated with additional administrative effort of including a critical habitat analysis in section 7 consultations for these three DPSs, (2) impacts to national security, and (3) the possible harm to our working relationship with Indian tribes and landowners and entities with conservation plans.

Economic Impacts

Our Economic Analysis sought to determine the impacts on land uses and

other activities from the designation of critical habitat, above and beyond—or incremental to—those “baseline” impacts due to existing or planned conservation efforts being undertaken due to other Federal, state, and local regulations or guidelines (NMFS, 2014b). Other Federal agencies, as well as state and local governments, may also seek to protect the natural resources under their jurisdiction. If compliance with the Clean Water Act or state environmental quality laws, for example, protects habitat for the species, such protective efforts are considered to be baseline protections and costs associated with these efforts are not quantified as impacts of critical habitat designation.

When critical habitat is designated, section 7 requires Federal agencies to ensure that their actions are not likely to result in the destruction or adverse modification of critical habitat, in addition to ensuring that the actions are not likely to jeopardize the continued existence of the species. The added administrative costs of considering critical habitat in section 7 consultations and the additional impacts of implementing project modifications to protect critical habitat are the direct result of the designation of critical habitat. These costs are not in the baseline, and are considered incremental impacts of the rulemaking.

Incremental economic impacts may include the direct costs associated with additional effort for future consultations, reinitiated consultations, new consultations occurring specifically because of the designation, and additional project modifications that would not have been required to avoid jeopardizing the continued existence of the species. Additionally, incremental economic impacts may include indirect impacts resulting from reaction to the potential designation of critical habitat (e.g., developing habitat conservation plans in an effort to avoid designation of critical habitat), triggering of additional requirements under State or local laws intended to protect sensitive habitat, and uncertainty and perceptual effects on markets.

To evaluate the potential administrative and project modification costs of designating critical habitat we examined our ESA section 7 consultation record for rockfishes for the years 2010 and 2011. As further explained in the supporting Economic Analysis (NMFS, 2014b), to quantify the economic impact of designation, we employed the following three steps:

(1) Define the geographic study area for the analysis, and identify the units of analysis (the “particular areas”). In

this case, we defined the five biogeographic Basins of the Puget Sound/Georgia Basin that encompass occupied marine areas as the particular areas.

(2) Identify potentially affected economic activities and determine how management may increase due to the designation of listed rockfish critical habitat, both in terms of project administration and potential project modification.

(3) Estimate the economic impacts associated with both potential administrative costs and costs from project modifications. In this critical habitat designation we did not identify potential systematic project modification costs (NMFS, 2014b).

We estimated that the additional effort to address adverse modification of critical habitat in an ESA section 7 consultation is equivalent to one third of the effort already devoted to the consultation to consider the species. This is based on estimates of additional USFWS effort for bull trout consultations in the Northwest, which was considered relevant to the current critical habitat designation (NMFS, 2014b). That is, for every 3 hours spent considering a jeopardy analysis for rockfishes, an additional hour would be needed to consider rockfish critical habitat. Based on that assumption, we estimated a total annualized incremental administrative cost of approximately \$123,000 (discounted at 7 percent) for designating the five specific areas as listed rockfish critical habitat. The greatest costs are associated with nearshore work, transportation, water quality, and utilities (see NMFS, 2014b for more details). The estimated annual incremental costs across the five biogeographic Basins range from \$32,100 in the San Juan/Strait of Juan de Fuca Basin to \$10,200 in Hood Canal (NMFS, 2014b).

For the second category of impacts, we consider it unlikely there will be incremental costs for project modifications specific to rockfish critical habitat for most individual project types. This is because of the existing high level of protection afforded by previous salmonid, green sturgeon and killer whale critical habitat designations that have generally similar biological features, and the protections already afforded listed rockfishes through the separate jeopardy analysis (see NMFS, 2014b for more details). The results of our Economic Analysis are discussed in greater detail in a separate report that is available for public review (NMFS, 2014b).

Impacts to National Security

During preparations for the proposed designation we sent a letter to the DOD seeking information to better understand their activities taking place in areas owned or controlled by them and the potential impact of designating critical habitat in these areas. We received two letters from the DOD in response to our initial inquiry. A single letter from the U.S. Air Force and U.S. Army stated that these services did not foresee any adverse impacts to their national security or training missions from proposed rockfish critical habitat designations. The second letter, from the U.S. Navy, identified 14 Restricted Areas, Operating Areas and Danger Zones (security zones) within the range of listed rockfishes in the five Basins of the Puget Sound. The Navy confirmed that it uses all of these security zones, and assessed the potential for critical habitat designation to adversely affect operations, testing, training, and other essential military activities. Of the 14 security zones identified by the Navy, only one area is already designated as critical habitat for other ESA-listed species (Southern Resident killer whales). The Navy letter identified several aspects of potential impacts to national security from critical habitat designation and requested that areas owned or controlled by the Navy be excluded from designation. We had several conversations with the Navy subsequent to their letter to further understand their uses of the areas, concerns identified in their response letter, and any related habitat protections resulting from Navy policies and initiatives (NMFS, 2014c).

The Navy sent us a letter and subsequent electronic communications in response to our proposed critical habitat designation. The Navy clarified that Hood Canal and Dabob Bay Naval Non-Explosive Torpedo Testing Area and Dabob Bay, Whitney Point Naval Restricted Area are covered by the INRMP for Naval Station Kitsap in addition to several other security areas (see above). In addition, the Navy specifically requested that Operating Area R-6713 (Navy 3) not be designated as critical habitat and requested clarification on our proposed nearshore designation in some areas of the Puget Sound. We contacted the Navy regarding their uses and concerns regarding our proposed critical habitat designation of Operating Area R-6713. In 2009 we designated critical habitat for green sturgeon (74 FR 52300; October 9, 2009). Prior to the green sturgeon final critical habitat designation the Navy provided us

language regarding how critical habitat designation for that species would affect their operations. The Navy stated that the impacts of green sturgeon critical habitat designation would be similar to listed rockfish critical habitat designation. We assessed the Navy's information regarding Operating Area R-6713 (see Appendix C of our section 4(b)(2) report).

Other Relevant Impacts—Impacts to Tribal Sovereignty and Self-governance

During preparations for the proposed designation we sent a letter to Puget Sound Indian tribes, notifying them of our intent to propose critical habitat for listed rockfishes. We identified several areas under consideration for critical habitat designation that overlap with Indian lands in each of the specific areas (see the final 4(b)(2) report and Figures 2 and 3). The federally recognized tribes with lands potentially affected are the Lummi, Swinomish, Tulalip, Puyallup, Squaxin Island, Skokomish, Port Gamble, and Port Madison. In addition to the economic impacts described above, designating these tribes' Indian lands would have an impact on Federal policies promoting tribal sovereignty and self-governance. The longstanding and distinctive relationship between the Federal and tribal governments is defined by treaties, statutes, executive orders, secretarial orders, judicial decisions, and agreements, which differentiate tribal governments from the other entities that deal with, or are affected by, the U.S. Government. This relationship has given rise to a special Federal trust responsibility involving the legal responsibilities and obligations of the United States toward Indian tribes with respect to Indian lands, tribal trust resources, and the exercise of tribal rights. Pursuant to these authorities, lands have been retained by Indian tribes or have been set aside for tribal use. These lands are managed by Indian tribes in accordance with tribal goals and objectives within the framework of applicable treaties and laws.

Tribal governments have a unique status with respect to salmon, steelhead, and other marine resources in the Pacific Northwest, where they are co-managers of these resources throughout the region. The co-manager relationship crosses tribal, Federal, and state boundaries, and addresses all aspects of the species' life cycle. The positive working relationship between the Federal government and tribes can be seen in Federal-tribal participation within the *U.S. v. Oregon* and *U.S. v. Washington* framework and the participation of tribes on interstate

(Pacific Fisheries Management Council) and international (Pacific Salmon Commission) management bodies. Additionally, there are innumerable local and regional forums and planning efforts in which the tribes are engaged with the Federal Government, including ESA section 6 species recovery grants to the tribes. While many of these activities currently concentrate on recovery of listed salmon and steelhead in Puget Sound, they nonetheless result in several benefits to habitats used by listed rockfishes through the conservation of habitats and prey sources of rockfishes (NMFS, 2014c).

Other Relevant Impacts—Impacts to Landowners/Entities With Contractual Commitments to Conservation

Section 10(a)(1)(B) of the ESA authorizes us to issue to non-Federal entities a permit for the incidental take of endangered and threatened species. This permit allows a non-Federal landowner/entity to proceed with an activity that is legal in all other respects, but that results in the incidental taking of a listed species (i.e., take that is incidental to, and not the purpose of, the carrying out of an otherwise lawful activity). The ESA specifies that an application for an incidental take permit (ITP) must be accompanied by a conservation plan, and specifies the content of such a plan. The purpose of such conservation plans is to describe and ensure that the effects of the permitted action on covered species are adequately minimized and mitigated, and that the action does not appreciably reduce the likelihood of the survival and recovery of the species. Conservation plans that cover habitat actions are common for terrestrial and freshwater species and can benefit species threatened by land use activities. Conservation plans that cover fisheries are less common and can benefit species and habitats threatened by fishing activities.

Conservation agreements with non-Federal landowners and other entities enhance species conservation by extending species' protections beyond those available through section 7 consultations. We have encouraged non-Federal landowners to enter into conservation agreements, based on a view that we can achieve greater species' conservation on non-Federal land through such partnerships than we can through coercive methods (61 FR 63854; December 2, 1996). In past critical habitat designations we have found there is a benefit to excluding some areas covered by conservation agreements when there is affirmative evidence that the conservation partner

considered exclusion beneficial to our relationship and beneficial to implementation of the conservation agreement (e.g., for Pacific salmon, 70 FR 52630; September 2, 2005). We considered the benefit of exclusion to be a conservation benefit to the affected species because of the enhanced implementation of the agreement and the incentive for others to enter into conservation agreements with us to further protect the species.

In the case of the listed rockfish species, there are two conservation agreements that partially or wholly overlap with critical habitat. The first is with the Washington DNR and covers geoduck harvest on lands managed by the department. The second is with the Washington Department of Fish and Wildlife (WDFW) and covers fisheries and research in Puget Sound that incidentally take the listed rockfishes and other listed species and may also affect rockfish habitat.

Determine Whether To Exercise the Discretion to Exclude

Benefits of critical habitat designation are those conservation benefits to the species, while benefits of exclusion result from avoiding the impacts of designation identified above. For the present designation, we decided to balance benefits of designation against benefits of exclusion because some impacts of designation implicate competing Federal values, such as national security and tribal sovereignty and self-governance (see NMFS, 2014c).

Benefits of Designation

The principal benefit of designating critical habitat is that ESA section 7 requires every Federal agency to ensure that any action it authorizes, funds, or carries out is not likely to result in the destruction or adverse modification of designated critical habitat. This complements the Section 7 provision that Federal agencies ensure their actions are not likely to jeopardize the continued existence of a listed species. The requirement that agencies avoid adversely modifying critical habitat is in addition to the requirement that they avoid jeopardy to the species, thus the benefit of designating critical habitat is "incremental" to the benefit that comes with listing. Another possible benefit is that the designation of critical habitat can serve to educate the public regarding the potential conservation value of an area. Systematic analysis and delineation of important rockfish habitat has not been previously conducted in the Puget Sound, so designating critical habitat may focus and contribute to conservation efforts by

clearly delineating areas that are important to species conservation.

Ideally the consideration and balancing of benefits would involve first translating all benefits into a common metric. Executive branch guidance from the Office of Management and Budget (OMB) suggests that benefits should first be monetized—converted into dollars. Benefits that cannot be monetized should be quantified (for example, numbers of fish saved). Where benefits can neither be monetized nor quantified, agencies are to describe the expected benefits (OMB, 2003).

It may be possible to monetize benefits of critical habitat designation for a threatened or endangered species in terms of willingness-to-pay (OMB, 2003). However, we are not aware of any available data at the scale of our designation (the five Basins of Puget Sound Sound) that would support such an analysis for listed rockfishes. In addition, section 4(b)(2) requires analysis of impacts other than economic impacts that are equally difficult to monetize, such as impacts to national security of including areas from critical habitat. In the case of rockfish designations, impacts to Northwest Indian tribes or to our program to promote voluntary conservation agreements are “other relevant” impacts that also may be difficult to monetize.

Because we could not monetize or quantify the conservation benefit of designating the particular areas as critical habitat, we qualitatively describe their conservation value to the listed species. The rockfish critical habitat we have identified consists of only five areas. Each area is a biogeographic Basin that represents a unique ecological setting with unique habitats and biological communities. This diversity of habitats is important to maintaining long-term viability of the DPSs. Four of the five areas are also relatively spatially isolated in terms of water circulation and exchange of some biota. Although we lack detailed genetic information to confirm that this isolation has led to reproductive isolation among Basins, it is likely that there is some degree of reproductive isolation and that the unique habitat conditions in each Basin have therefore resulted in important adaptations. The diversity this creates in the population, like the diversity in habitats, is important to long-term viability. These factors suggest that all of the populations and Basins are important in maintaining the diversity and spatial structure of each DPS. Though we have not yet developed a final Recovery Plan for these DPSs, it is likely that all five areas are important to recovery of the

listed DPSs and therefore have high conservation value (NMFS, 2014a).

Balancing Economic Impacts

In our 2005 final and 2013 proposed critical habitat designations for salmon and steelhead, we balanced conservation benefits of designation against economic benefits of exclusion and excluded particular areas for many of the affected species. Our approach was informed by both biology and policy (78 FR 2725, January 14, 2013; 70 FR 52630, September 2, 2005). In deciding to balance benefits, we noted that salmon and steelhead are widely distributed and their range includes areas that have both high and low conservation value; thus, it may be possible to construct different scenarios for achieving conservation. We also noted Administration policy regarding regulations, as expressed in Executive Order 12866, which directs agencies to select regulatory approaches that “maximize net benefits,” and to “design regulations in the most cost-effective manner to achieve the regulatory objective.”

For the salmon and steelhead designations, we used a cost effectiveness approach in which we identified areas to consider for economic exclusion by balancing relative conservation value against relative economic impact. Where the relative conservation value of an area was lower than the relative economic impact, we considered the area eligible for exclusion. Relying on policies that promote conservation of threatened and endangered species in general and salmon in particular, we did not consider areas for exclusion if exclusion would significantly impede conservation. We concluded that exclusion of high conservation value areas would significantly impede conservation and therefore we did not consider any high conservation value areas for exclusion for salmon and steelhead.

In considering economic exclusions for listed rockfishes, we considered the following factors: (1) Section 2 of the ESA provides that a purpose of the act is “to provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved”; (2) in listing the three listed rockfish DPSs under the ESA, we concluded that degradation of rocky habitat, loss of eelgrass and kelp, introduction of non-native habitat-modifying species, and degraded water quality were all threats to the species; (3) that rocky habitats are rare in Puget Sound and have been affected by or are threatened by derelict fishing gear,

development, and construction and dredging activities; (4) as described above, there are only five habitat areas and all are of high conservation value; and (5) the economic impacts of designating any particular area are small (the largest impact is \$32,100 in the San Juan/Strait of Juan de Fuca Basin), as is the economic impact of designating the entire area (\$123,000).

For these reasons, we conclude that the economic benefit of excluding any of these particular areas does not outweigh the conservation benefit of designation. Therefore, none of the areas were eligible for exclusion based on economic impacts.

Balancing Impacts to Tribal Sovereignty and Self-Determination

We balanced the conservation benefits to rockfishes of designation against the benefits of exclusion for Indian lands in light of the unique Federal tribal relationship, the unique status of Indian lands, and the Federal policies promoting tribal sovereignty and self-determination, among others. Indian lands potentially affected by a critical habitat designation occur within the range of the listed rockfishes and are specific to nearshore juvenile rearing sites for canary rockfish and bocaccio. We are not designating any nearshore areas of Puget Sound as critical habitat for yelloweye rockfish (NMFS, 2014a). There are eight tribes with Indian lands that overlap the critical habitat in all five Basins. Approximately 64.1 lineal miles (103 km) of shoreline within reservation boundaries overlap with the nearshore component of critical habitat.

The principal benefit of designating critical habitat is section 7’s requirement that Federal agencies ensure their actions are not likely to result in adverse modification of that habitat. To understand the benefit of designating critical habitat on Indian lands, we considered the number of miles of shoreline affected, and the types of activities occurring there that would be likely to undergo a section 7 consultation along this shoreline area. The types of activities occurring in these areas that would be likely to undergo a section 7 consultation include activities associated with: Nearshore development, utilities, dredging, water quality projects, transportation, and other project types.

The benefit of excluding these areas is that Federal agencies acting on behalf of, funding, or issuing permits to the tribes would not need to reinstate consultation on ongoing activities for which consultation has been completed. Reinitiation of consultation would likely require some commitment of

resources on the part of the affected tribe. Moreover, in a reinitiated consultation, or in any future consultation, it is possible that tribes may be required to modify some of their activities to ensure the activities would not be likely to adversely modify the critical habitat (though given the small proportion of shoreline length with essential features, and tribal shoreline management, this is unlikely). The benefits of excluding Indian lands from designation include: (1) The furtherance of established national policies, our Federal trust obligations, and our deference to the tribes in management of natural resources on their lands; (2) the maintenance of effective long-term working relationships to promote the conservation of rockfishes; (3) the allowance for continued meaningful collaboration and cooperation in scientific work to learn more about the conservation needs of the species; and (4) continued respect for tribal sovereignty over management of natural resources on Indian lands through established tribal natural resource programs. We also considered the degree to which the tribes believe designation will affect their participation in regional management forums and their ability to manage their lands.

Based on our consideration, and given the preceding factors, we concluded that the benefits to conservation of listed rockfishes from full tribal participation in Puget Sound recovery efforts mitigates the potential loss of conservation benefits that could result from designation of tribal lands as critical habitat. With this mitigating conservation benefit in mind, we further concluded that the benefits to tribal governments, with whom the Federal Government has a unique trust relationship, particularly with regard to land held by the Federal Government in trust for the tribes, outweigh the conservation benefits of designation for listed rockfishes (NMFS, 2014c).

The Indian lands specifically excluded are those defined in the Secretarial Order 3206, including: (1) Lands held in trust by the United States for the benefit of any Indian tribe; (2) lands held in trust by the United States for any Indian tribe or individual subject to restrictions by the United States against alienation; (3) fee lands, either within or outside the reservation boundaries, owned by the tribal government; and (4) fee lands within the reservation boundaries owned by individual Indians. Our consideration of whether these exclusions would result in extinction of listed rockfishes is described below.

Balancing Impacts to Landowners/Entities With Contractual Commitments to Conservation

Our consideration of the DNR and WDFW conservation plans is described in detail in the ESA Section 4(b)(2) Report (NMFS, 2014c). We balanced the conservation benefits to rockfishes of critical habitat designation against the benefits of exclusion (referring to the impacts of designation section above) of the areas covered in each conservation plan. Each plan covers several activities that may take listed species and harm critical habitat in Puget Sound. Congress added section 10 to the ESA to encourage “creative partnerships between the private sector and local, state, and Federal agencies for the protection of endangered species and habitat conservation” (*H.R. Rep. No. 835, 97th Congress, 2nd Session 31; Reprinted in 1982 U.S. Code Congressional and Administrative News 2807, 2831*). If excluding areas from critical habitat designation promotes such conservation partnerships, such exclusions may have conservation benefits that offset the conservation benefit that would have resulted from designation. The covered areas of the WDNR conservation plan overlap with approximately 30,000 acres of nearshore critical habitat for canary rockfish and bocaccio. The covered areas of the WDFW conservation plan overlap with the entire critical habitat for yelloweye rockfish, canary rockfish, and bocaccio. DNR covered activities are geoduck research and harvest management. WDFW covered activities are the management of recreational bottom fish fishing and commercial shrimp trawls. The types of activities occurring in these areas that would be likely to undergo a section 7 consultation include nearshore development, dredging, aquaculture operations, fisheries management, alternative energy projects and cable laying, and others (NMFS, 2014a).

In general, the benefits of designating the covered areas of each conservation plan is that once critical habitat is designated, section 7(a)(2) of the ESA provides that Federal agencies must ensure any actions they authorize, fund, or carry out are not likely to result in the destruction or adverse modification of designated critical habitat. An additional benefit of inclusion is that a systematic analysis and delineation of important rockfish habitat has not been previously conducted in the Puget Sound. Thus, for non-Federal activities occurring in the covered areas, designation may raise public awareness of habitats important to rockfishes and encourage additional conservation

measures and voluntary conservation agreements within the section 10 program. The benefits of designating areas covered by these two conservation plans may be less than what they would be on areas not covered by conservation plans because of the fact that the permit holder has put conservation measures in place through provisions of the plan. These measures provide protection when actions are allowed that could affect critical habitat (geoduck harvest and management by DNR, and fisheries by WDFW). However, these conservation plans are unlike other land-based conservation plans in the Northwest (such as forestry conservation plans) because the DNR and WDFW plans cover a small subset of potential actions that could be affected by future Federal actions in Puget Sound (i.e., Federal permits for nearshore development, fisheries that cause new derelict fishing nets, tidal energy or cable-laying, and others).

The benefits of excluding these covered areas from designation include the potential furtherance of our ongoing relationship with these entities; in particular, the potential that the exclusion of these areas may provide an incentive for other entities to seek conservation plans, and the general promotion of the section 10 conservation program. Conservation agreements on non-federally controlled areas of Puget Sound provide important benefits to listed species. Section 7 applies to only Federal agency actions. Its requirements protect listed fishes only when a Federal permit or funding is involved; thus, its reach is limited. Neither DNR nor WDFW identified any potential impacts to our relationship or implementation of each conservation plan.

For each rockfish DPS we considered the areas each conservation plan covered and the types of Federal activities in those areas that would likely undergo section 7 consultation. We also considered the degree to which DNR and WDFW believe the designation would affect the ongoing relationship that is essential to the continued successful implementation of the conservation plan and the extent to which exclusion provides an incentive to other entities.

Based on our consideration, and given the following factors, we concluded that the benefits of excluding the areas covered by each conservation plan do not outweigh the benefits of designation. We considered the following factors in reaching this conclusion: (1) DNR and WDFW did not identify any impacts to our ongoing relationship, nor did they comment on

our proposed designation relative to their conservation plans and critical habitat; (2) DNR and WDFW did not identify any impacts of critical habitat designation to their implementation of the existing conservation plans; and (3) the DNR and WDFW conservation plans cover only a subset of activities that could affect rockfish critical habitat conducted by other entities such as private landowners, municipalities, and Federal agencies in the covered areas. Thus, designation would not impact our relationship with DNR and WDFW nor harm the implementation of their conservation plans. In general, designation would benefit rockfish conservation by enabling section 7 consultations for activities not covered by each conservation plan to ensure adverse modification is avoided by Federal activities.

Balancing Impacts to National Security

Based on information provided by the three branches of the military on impacts to national security of potential critical habitat designations described above, we consulted with DOD to better understand the potential impact of designating critical habitat at these sites. The DOD confirmed that all of the security zones are used by the Navy, and confirmed the potential for critical habitat designation to impact national security by adversely affecting their ability to conduct operations, testing, training, and other essential military activities. The Navy letter identified several aspects of potential impacts from critical habitat designation that include the possible prevention, restriction, or delay of training or testing exercises and delayed response time for ship deployments. We had several conversations with the Navy subsequent to its letter to further understand its uses of the security zones concerns identified in its response letter, and any related habitat protections derived by Navy policies and initiatives. We also had further discussions with the Navy regarding the extent of the proposed designation associated with these sites. The Navy agreed to refine the delineation of offshore areas in Puget Sound where the Navy has established security zones. Similar to the salmonid critical habitat designation (NMFS, 2005) the Navy agreed that the military zone could be designated in all or a portion of the nearshore in one of their security zones that is not covered by an INRMP, and we clarified which areas of the nearshore are designated as critical habitat in our final 4(b)(2) report (see NMFS, 2014c) and in this final rule. Because many of the activities affecting rockfishes in the nearshore zone are

land-based, this refinement allowed us to retain most of the conservation benefit of designating nearshore areas as critical habitat in one area while still retaining the benefit to national security of excluding offshore military areas (NMFS, 2014c).

We balanced the conservation benefits of designation to rockfishes against the benefits of exclusion for security zones as ultimately defined by the Navy in the Puget Sound/Georgia Basin. Prior to the publication of the proposed rule (78 FR 47635; August 6, 2013) the Navy requested that 14 areas be excluded from critical habitat designation, including four in the San Juan/Strait of Juan de Fuca Basin, three in Hood Canal, two in the Whidbey Basin, four in the Main Basin, and one in South Puget Sound based on the impacts to national security. In response to the proposed rule the Navy clarified that Hood Canal and Dabob Bay Naval Non-Explosive Torpedo Testing Area and Dabob Bay, Whitney Point Naval Restricted Area are covered by the INRMP for Naval Station Kitsap. The Navy also clarified that the two Naval Restricted Areas in the Strait of Juan de Fuca, Eastern End; off the Westerly Shore of Whidbey Island, the Port Townsend, Indian Island, Walan Point Naval Restricted Area, Port Orchard Naval Restricted Area and the Puget Sound, Manchester Fuel Depot, Naval Restricted Area are also covered by an INRMP. For the security zones that occur solely within the nearshore we did not conduct the balancing exercise, as each falls completely within the provisions of the Sikes Act.

The factors we consider relevant to assessing the impact to national security and the benefits of exclusion include: (1) The percent of the military area that would be designated; and (2) the importance of the area activity to national security and likelihood an activity would need to be changed to avoid adverse modification.

The factors we consider relevant to assessing the benefits of designation to rockfish conservation include: (1) The percent of the nearshore and deepwater critical habitat that would be designated in that Basin; (2) uniqueness and conservation role of the habitat in particular DOD areas; (3) the likelihood that Navy activities would destroy or adversely modify critical habitat; and (4) the likelihood habitat would be adversely modified by other Federal or non-Federal activities, considering Navy protections (this factor considers the type and frequency of Navy actions that occur in each site and their potential effect on rockfish habitat features, which informs the benefit to

conservation that would occur by a section 7 consultation that considers rockfish critical habitat).

All but the quantitative factors were given a qualitative rating of high, medium, or low (NMFS, 2014c). Based on our analysis, we are excluding all but one of the areas requested by the Navy. We do not exclude Operating Area R-6713 (Navy 3). We contacted the Navy regarding its uses and concerns regarding our proposed critical habitat designation of this area, and assessed the additional information provided to us by the Navy. We continue to conclude that the benefits to national security of excluding this particular area do not outweigh the benefits to rockfish conservation of designating it. This area is a polygon off the western side of Naval Air Station Whidbey Island (appearing on NOAA Chart 18400) which is used in conjunction with the restricted area under 33 CFR 334.1180 for surface vessel training activities. For this area we found moderate benefits of exclusion to the Navy because the percent of the military area that would be designated is relatively small, the area is only sporadically used by the Navy, suggesting little value of the area to the Navy mission, and the additional analysis required for consultation addressing the potential for adverse modification is likely minimal (NMFS, 2014c). We found moderate benefits to designating the area as critical habitat because of the uniqueness and conservation role of the area, and the likelihood that habitat could be adversely modified by other Federal or non-Federal activities, and considering Navy restrictions on non-Navy activities (NMFS, 2014c). Because the benefit of exclusion does not outweigh the benefit of designation, we do not exclude Navy 3. The excluded areas total approximately 15.7 nearshore sq mi (40.7 sq km) and 20.1 square miles (52.1 sq km) of deepwater critical habitat.

Critical habitat is designated in a narrow nearshore zone (from the extreme high tide datum down to MLLW) within the Admiralty Inlet Naval Restricted Area. Critical habitat is designated from extreme high tide to a depth of 30 meters at Carr Inlet Naval Restricted Area. The following Department of Defense areas are not included as critical habitat:

(1) Small Arms Danger Zone off Western Side of Naval Air Station Whidbey Island and additional Accident Potential Zone restricted areas—In the waters located in the San Juan De Fuca Strait beginning on the beach of NAS Whidbey Island, Oak Harbor, Washington at latitude 48°19'20.00" N, longitude 122°42'6.92"

W; thence southerly, along the mean high water mark, to latitude 48°17'41" N, longitude 122°43'35" W; thence southwesterly to latitude 48°17'23" N, longitude 122°45'14" W; thence northerly to latitude 48°20'00" N, longitude 122°44'00" W; thence easterly, landward to the point of origin.

Accident Potential Zone Area No. 1 is bounded by a line commencing at latitude 48°20'57" N, longitude 122°40'39" W; thence to latitude 48°20'40" N, longitude 122°42'59" W; thence to latitude 48°21'19" N, longitude 122°43'02" W; thence to latitude 48°21'13" N, longitude 122°40'26" W; and thence along the shore line to the point of origin. Accident Potential Zone Area No. 2 is bounded by a line commencing at latitude 48°21'53" N, longitude 122°40'00" W; thence to latitude 48°23'12" N, longitude 122°41'17" W; thence to latitude 48°23'29" N, longitude 122°40'22" W; thence to latitude 48°22'21" N, longitude 122°39'50" W; and thence along the shore line to the point of origin.

(2) Strait of Juan de Fuca Naval Air-to-Surface Weapon Range Restricted Area—A circular area immediately west of Smith Island with a radius of 1.25 nautical mi (2.32 km) having its center at latitude 48°19'11" N and longitude 122°54'12" W.

(3) Hood Canal and Dabob Bay Naval Non-Explosive Torpedo Testing Area—All waters of Hood Canal between latitude 47°46'00" N and latitude 47°42'00" N, exclusive of navigation lanes one-fourth nautical mile (0.46 km) wide along the west shore and along the east shore south from the town of Bangor (latitude 47°43'28" N). All waters of Dabob Bay beginning at latitude 47°39'27" N, longitude 122°52'22" W; thence northeasterly to latitude 47°40'19" N, longitude 122°50'10" W; thence northeasterly to a point on the mean high water line at Takutsko Pt.; thence northerly along the mean high water line to latitude 47°48'00" N; thence west on latitude 47°48'00" N to the mean high water line on the Bolton Peninsula; thence southwesterly along the mean high water line of the Bolton Peninsula to a point on longitude 122°51'06" W; thence south on longitude 122°51'06" W to the mean high water line at Whitney Pt.; thence along the mean high water line to a point on longitude 122°51'15" W; thence southwesterly to the point of beginning. The nearshore from Tsuktsko Pt. 47°41'30.0" N latitude, 122°49'48" W longitude to the north at 47°50'0.0" N latitude, 122°47'30" W longitude.

(4) Admiralty Inlet Naval Restricted Area—This area begins at Point Wilson

Light thence southwesterly along the coast line to latitude 48°07'00" N; thence northwesterly to a point at latitude 48°15'00" N longitude 123°00'00" W; thence due east to Whidbey Island; thence southerly along the coast line to latitude 48°12'30" N; thence southerly to the point of beginning.

(5) Port Gardner, Everett Naval Base, Naval Restricted Area—The waters of Port Gardner and East Waterway surrounding Naval Station Everett begin at a point near the northwest corner of Naval Station Everett at latitude 47°59'40" N, longitude 122°13'23.5" W and thence to latitude 47°59'40" N, longitude 122°13'30" W; thence to latitude 47°59'20" N, longitude 122°13'33" W; thence to latitude 47°59'13" N, longitude 122°13'38" W; thence to latitude 47°59'05.5" N, longitude 122°13'48.5" W; thence to latitude 47°58'51" N, longitude 122°14'04" W; thence to latitude 47°58'45.5" N, longitude 122°13'53" W; thence to latitude 47°58'45.5" N, longitude 122°13'44" W; thence to latitude 47°58'48" N, longitude 122°13'40" W; thence to latitude 47°58'59" N, longitude 122°13'30" W; thence to latitude 47°59'14" N, longitude 122°13'18" W (Point 11); thence to latitude 47°59'13" N, longitude 122°13'12" W; thence to latitude 47°59'20" N, longitude 122°13'08" W; thence to latitude 47°59'20" N, longitude 122°13'02.5" W, a point upon the Naval Station's shore in the northeast corner of East Waterway.

(6) Hood Canal, Bangor Naval Restricted Areas—The Naval restricted area described in 33 CFR 334.1220 has two areas. Area No. 1 is bounded by a line commencing on the east shore of Hood Canal in relation to the property boundary and area No. 2 encompasses waters of Hood Canal with a 1,000 yard (0.91 km) radius diameter from a central point. Area No. 1 is bounded by a line commencing on the east shore of Hood Canal at latitude 47°46'18" N longitude 122°42'18" W; thence to latitude 47°46'32" N, longitude 122°42'20" W; thence to latitude 47°46'38" N, longitude 122°42'52" W; thence to latitude 47°44'15" N, longitude 122°44'50" W; thence to latitude 47°43'53" N, longitude 122°44'58" W; thence to latitude 47°43'17" N, longitude 122°44'49" W. Area 2 is waters of Hood Canal within a circle of 1,000 yards (0.91 km) diameter centered on a point located at latitude 47°46'26" N, longitude 122°42'49" W.

(7) Port Orchard Naval Restricted Area—The Naval restricted area described in 33 CFR 334.1230 is

shoreward of a line beginning at a point on the west shoreline of Port Orchard bearing 90° from stack (at latitude 47°42'01" N, longitude 122°36'54" W); thence 90°, approximately 190 yards (174 m), to a point 350 yards (320 m) from stack; thence 165°, 6,000 yards (5.49 km), to a point bearing 179°, 1,280 yards (1.17 km), from Battle Point Light; thence westerly to the shoreline at latitude 47°39'08" N (approximate location of the Brownsville Pier).

(8) Sinclair Inlet Naval Restricted Areas—The Naval restricted area described in 33 CFR 334.1240 to include: Area No. 1—All the waters of Sinclair Inlet westerly of a line drawn from the Bremerton Ferry Landing at latitude 47°33'48" N, longitude 122°37'23" W; on the north shore of Sinclair Inlet and latitude 47°32'52" N, longitude 122°36'58" W; on the south shore of Sinclair Inlet; and Area No. 2—That area of Sinclair Inlet to the north and west of an area bounded by a line commencing at latitude 47°33'43" N, longitude 122°37'31" W thence south to latitude 47°33'39" N, longitude 122°37'27" W thence southwest to latitude 47°33'23" N, longitude 122°37'45" W thence southwest to latitude 47°33'19" N, longitude 122°38'12" W thence southwest to latitude 47°33'10" N, longitude 122°38'19" W thence southwest to latitude 47°33'07" N, longitude 122°38'29" W thence west to latitude 47°33'07" N, longitude 122°38'58" W thence southwest to latitude 47°33'04" N, longitude 122°39'07" W thence west to the north shore of Sinclair Inlet at latitude 47°33'04.11" N, longitude 122°39'41.92" W.

(9) Dabob Bay, Whitney Point Naval Restricted Area—The Naval restricted area described in 33 CFR 334.1260 beginning at the high water line along the westerly shore of Dabob Bay at the Naval Control Building located at latitude 47°45'36" N and longitude 122°51'00" W. The western shoreline boundary is 100 yards (91 m) north and 100 yards (91 m) south from that point. From the north and south points, go eastward 2,000 yards (1.83 km) into Dabob Bay. The eastern boundary is a virtual vertical line between the two points (200 yards (189.2 m) in length).

(10) Carr Inlet, Naval Restricted Area—The Naval restricted area described in 33 CFR 334.1250 to include: The area in the Waters of Carr Inlet bounded on the southeast by a line running from Gibson Point on Fox Island to Hyde Point on McNeil Island, on the northwest by a line running from Green Point (at latitude 47°16'54" N, longitude 122°41'33" W) to Penrose Point; plus that portion of Pitt Passage

extending from Carr Inlet to Pitt Island, and that portion of Hale Passage extending from Carr Inlet southeasterly to a line drawn perpendicular to the channel 500 yards (457 m)

northwesterly of the Fox Island Bridge.

(11) Port Townsend, Indian Island, Walan Point Naval Restricted Area—The Naval restricted area described in 33 CFR 334.1270 to include: The waters of Port Townsend Bay bounded by a line commencing on the north shore of Walan Point at latitude 48°04'42" N, longitude 122°44'30" W; thence to latitude 48°04'50" N, longitude 122°44'38" W; thence to latitude 48°04'52" N, longitude 122°44'57" W; thence to latitude 48°04'44" N, longitude 122°45'12" W; thence to latitude 48°04'26" N, longitude 122°45'21" W; thence to latitude 48°04'10" N, longitude 122°45'15" W; thence to latitude 48°04'07" N, longitude 122°44'49" W; thence to a point on the Walan Point shoreline at latitude 48°04'16" N, longitude 122°44'37" W.

(12) NAS Whidbey Island, Crescent Harbor—The waters of Puget Sound adjacent to Whidbey Island Naval Air Station that include: the waters of Crescent Harbor starting at Maylor Point at latitude 48°16'4" N, longitude 122°37'28" W; thence to 6/10 mile (0.97 km) south of Maylor Point latitude 48°15'32" N, longitude 122°37'28" W; thence to 6/10 mile (0.97 km) south of Polnell Point latitude 48°15'47", longitude 122°33'25" W; thence to 500 ft (152 m) southeast of Polnell Point latitude 48°16'16" N, longitude 122°33'27" W; thence to Polnell Point latitude 48°16'19" N, longitude 122°33'34" W.

(13) Puget Sound, Manchester Fuel Depot, Naval Restricted Areas—The waters of Puget Sound surrounding the

Manchester Fuel Depot bounded by a line commencing along the northern shoreline of the Manchester Fuel Depot at latitude 47°33'55" N, longitude 122°31'55" W; thence to latitude 47°33'37" N, longitude 122°31'50" W; thence to latitude 47°33'32" N, longitude 122°32'06" W; thence to latitude 47°33'45.9" N, longitude 122°32'16.04" W, a point in Puget Sound on the southern shoreline of the Manchester Fuel Depot then back to the original point.

Exclusion Will Not Result in Extinction of the Species

Section 4(b)(2) of the ESA limits our discretion to exclude areas from designation if exclusion will result in extinction of the species. We have not excluded any habitat areas based on economic impacts or 10(a)(1)(B) permits (conservation plans). We have excluded 64.1 lineal mi (103.1 km) of marine habitat adjacent to Indian lands and approximately 35.8 sq mi (92.7 sq km) of marine habitat area (15.7 sq mi of nearshore, 20.1 sq mi of deepwater) controlled by the Navy as described above. We conclude that excluding Indian lands—and thereby furthering the Federal government's policy of promoting respect for tribal sovereignty and self-governance—in addition to several areas controlled by the Navy, will not result in extinction of listed rockfishes. Listed rockfish habitat on Indian lands represents a small proportion of total area occupied by these DPSs, and the Tribes are actively engaged in fisheries management, habitat management and Puget Sound ecosystem recovery programs that benefit listed rockfishes.

Listed rockfish habitat within areas controlled by the Navy represents approximately 8 percent of the

nearshore area and approximately 6 percent of the deepwater area we determined to have essential features. In addition to the small size of these exclusions, the Navy actively seeks to protect actions that would impact their mission and these protections provide ancillary protections to rockfish habitat by restricting actions that may harm the Navy mission and rockfishes in the respective area (NMFS, 2014c). Thus the benefit of designating these areas as critical habitat would be reduced.

For the following reasons, we conclude that the exclusions described above, in combination, will not result in the extinction of the yelloweye rockfish, canary rockfish or bocaccio DPSs: (1) The Indian land exclusions involve nearshore habitats that are already managed by the tribes for conservation; (2) the Navy exclusions involve nearshore and deepwater habitats that are already afforded some protections by the Navy, and (3) the extent of Indian lands exclusions and Navy exclusions are spread amongst each of the five biogeographic Basins of Puget Sound, and cumulatively total a fraction of the overall habitats that have essential features for listed rockfishes.

Critical Habitat Designation

In total we designate approximately 590.4 square miles (1,529 sq km) of nearshore habitat for canary rockfish and bocaccio, and 414.1 sq mi (1,072.5 sq km) of deepwater habitat for yelloweye rockfish, canary rockfish and bocaccio within the geographical area occupied by the DPSs (Figures 2 and 3). Aside from some deepwater areas designated as critical habitat for rockfishes in Hood Canal, all other critical habitat overlaps with designated critical habitat for other species.

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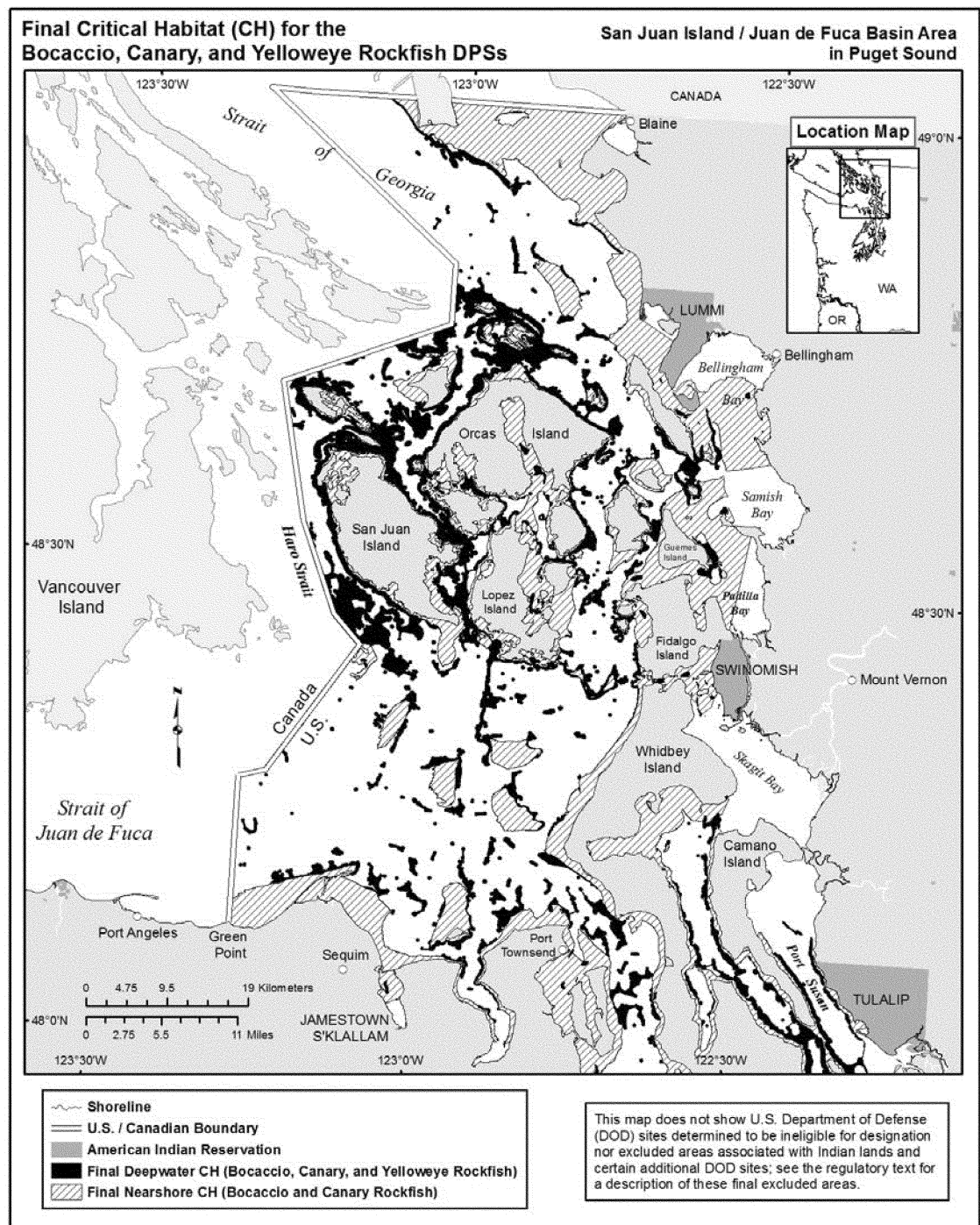


Figure 2. Critical Habitat for ESA-listed rockfishes in the northern portion of the Puget Sound area.

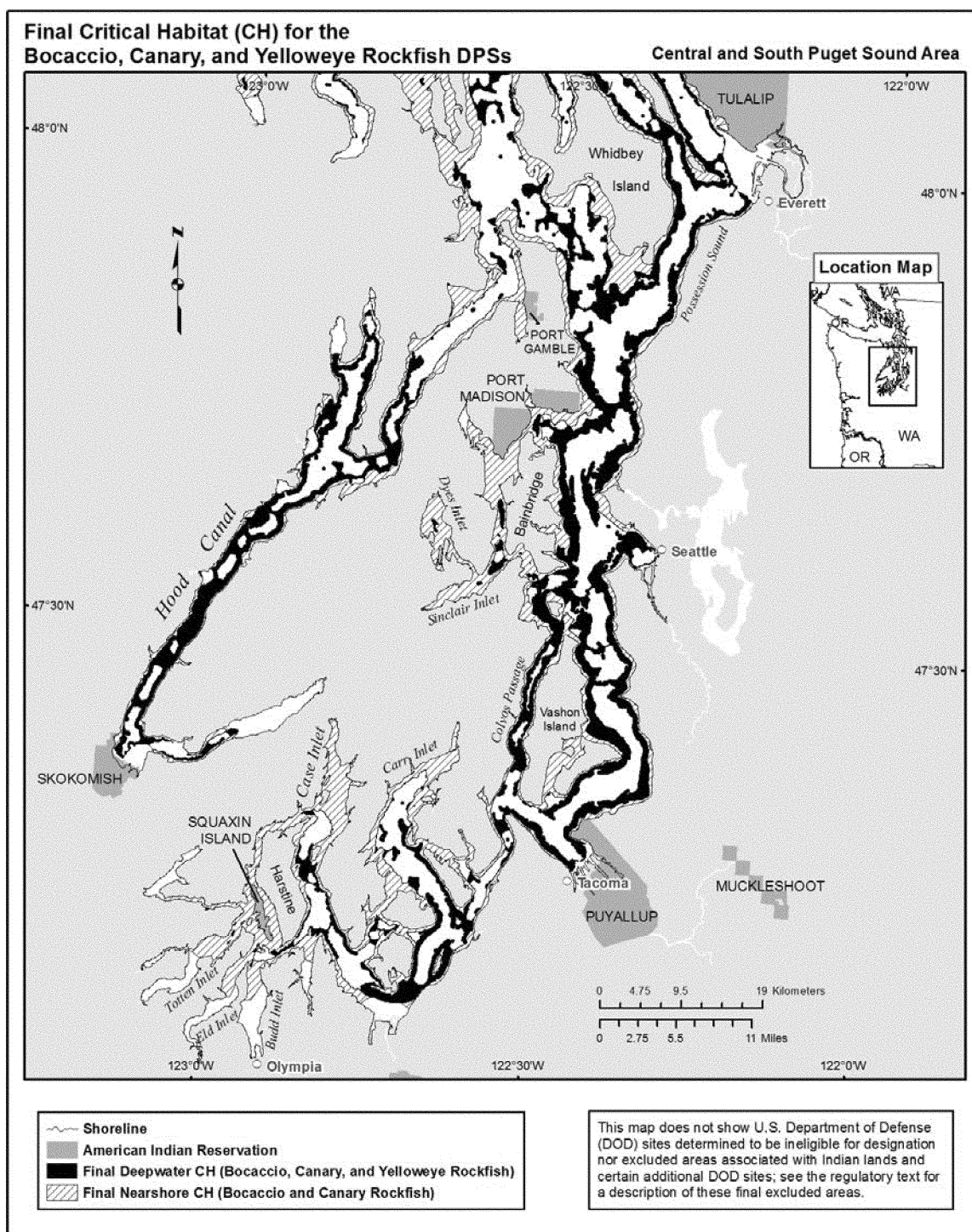


Figure 3. Critical Habitat for ESA-listed rockfishes in the southern portion of the Puget Sound area.

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Other co-occurring ESA-listed species with designated critical habitat that, collectively, almost completely overlap with rockfish critical habitat include Pacific salmon (70 FR 52630; September 2, 2005), North American green sturgeon (74 FR 52300; October 9, 2009),

Southern Resident killer whales (71 FR 69054; November 29, 2006), and bull trout (75 FR 63898; October 18, 2010). The areas designated are all within the geographical area occupied by the species and contain physical and biological features essential to the conservation of the species and that may

require special management considerations or protection. No unoccupied areas were identified that are considered essential for the conservation of the species. All of the areas designated have high conservation value (NMFS, 2014a). As a result of the balancing process for some military

areas and tribal areas described above, we are proposing to exclude from the designation small areas listed in Table 2 (see Figures 2 and 3 for locations of tribal lands). As a result of the balancing process for tribal areas we concluded that the benefits of excluding these areas outweigh the benefits of designation (NMFS, 2014c). As a result of the balancing process for economic impacts described above, we conclude that the economic benefit of excluding any of these particular areas does not outweigh the conservation benefit of designation. Therefore none of the areas were eligible for exclusion based on economic impacts. As a result of the balancing process for areas covered by Conservation Plans we concluded that the benefits of excluding the areas covered by each conservation plan do not outweigh the benefits of designation (NMFS, 2014c).

On May 1, 2012, NMFS and the USFWS revised the critical habitat implementing regulations to eliminate the requirement to publish textual descriptions of proposed (NMFS only)

and final (NMFS and USFWS) critical habitat boundaries in the Regulation Promulgation section of the **Federal Register** for codification and printing in the CFR (77 FR 25611; May 1, 2012).

The regulations instead provide that the map(s), as clarified or refined by any textual language within the preamble of the proposed or final rule, constitutes the definition of the boundaries of a critical habitat (50 CFR 17.94(b), 226.101, 424.12(c), 424.16(b) and (c)(1)(ii), and 424.18(a)). The revised regulations provide that the boundaries of critical habitat as mapped or otherwise described in the Regulation Promulgation section of a rulemaking published in the **Federal Register** will be the official delineation of the designation (50 CFR 424.12). In this final designation we include some latitude-longitude coordinates (to delineate certain DOD controlled security zone boundaries) to provide clarity on the location of DOD areas excluded, but also rely on the maps to depict critical habitat for yelloweye

rockfish, canary rockfish and bocaccio. The GIS data from which the maps have been generated are included in the administrative record and located on our Web site.

Section 3(5)(A)(ii) of the ESA authorizes the designation of “specific areas outside the geographical area occupied at the time [the species] is listed” if these areas are essential for the conservation of the species. Regulations at 50 CFR 424.12(e) emphasize that the agency “shall designate as critical habitat areas outside the geographical area presently occupied by a species only when a designation limited to its present range would be inadequate to ensure the conservation of the species.” We conducted a review of the documented occurrences of each listed rockfish in the five biogeographic Basins (NMFS, 2014a). We found that each of the Basins is currently occupied by yelloweye rockfish, canary rockfish, and bocaccio. We have not identified any unoccupied areas as candidates for critical habitat designation.

TABLE 2—HABITAT AREAS WITHIN THE GEOGRAPHICAL RANGE OF FOR YELLOWEYE ROCKFISH, CANARY ROCKFISH AND BOCACCIO EXCLUDED FROM CRITICAL HABITAT

Specific area	Conservation value	Total annualized estimated economic impacts (7%)	Economic exclusions	DOD areas excluded from critical habitat	Indian lands exclusions by “particular areas”	Exclusions for conservation plan permit holders
San Juan/Straits of Juan de Fuca.	High	\$32,100	No	Yes	Yes	No.
Whidbey Basin	High	30,100	No	Yes	Yes	No.
Main Basin	High	29,000	No	Yes	Yes	No.
Hood Canal	High	10,200	No	Yes	Yes	No.
South Puget Sound	High	21,200	No	Yes	Yes	No.
Totals	na	123,000	0	20.1 sq mi deep-water. 15.7 sq mi near-shore.	64.1 lineal mi	0.

Effects of Critical Habitat Designation

Section 7(a)(2) of the ESA requires Federal agencies to ensure that any action authorized, funded, or carried out by the agency (agency action) is not likely to jeopardize the continued existence of any threatened or endangered species or destroy or adversely modify designated critical habitat.

When a species is listed or critical habitat is designated, Federal agencies must consult with NMFS on any agency actions to be conducted in an area where the species is present or that may affect the species or its critical habitat. During the consultation, we evaluate the agency action to determine whether the action may adversely affect listed

species or critical habitat and issue our findings in a biological opinion or concurrence letter. If we conclude in the biological opinion that the agency action would likely result in the destruction or adverse modification of critical habitat, we would also recommend any reasonable and prudent alternatives to the action. Reasonable and prudent alternatives (defined in 50 CFR 402.02) are alternative actions identified during formal consultation that can be implemented in a manner consistent with the intended purpose of the action, that are consistent with the scope of the Federal agency’s legal authority and jurisdiction, that are economically and technologically feasible, and that would avoid the

destruction or adverse modification of critical habitat.

Regulations at 50 CFR 402.16 require Federal agencies that have retained discretionary involvement or control over an action, or where such discretionary involvement or control is authorized by law, to reinstate consultation on previously reviewed actions in instances where: (1) Critical habitat is subsequently designated; or (2) new information or changes to the action may result in effects to critical habitat not previously considered in the biological opinion. Consequently, some Federal agencies may request reinitiation of a consultation or conference with us on actions for which formal consultation has been completed,

if those actions may affect designated critical habitat or adversely modify or destroy critical habitat.

Activities subject to the ESA section 7 consultation process include activities on Federal lands and activities on private or state lands requiring a permit from a Federal agency (e.g., a Clean Water Act, Section 404 dredge or fill permit from U.S. Army Corps of Engineers (USACE)) or some other Federal action, including funding (e.g., Federal Highway Administration funding for transportation projects). ESA section 7 consultation would not be required for Federal actions that are not likely to affect listed species or critical habitat and for actions on non-Federal and private lands that are not Federally funded, authorized, or carried out.

Activities Affected by Critical Habitat Designation

ESA section 4(b)(8) requires in any final regulation to designate critical habitat an evaluation and brief description of those activities (whether public or private) that may adversely modify such habitat or that may be affected by such designation. A wide variety of activities may affect the critical habitat and may be subject to the ESA section 7 consultation process when carried out, funded, or authorized by a Federal agency. These include water and land management actions of Federal agencies (e.g., the Department of Defense, USACE, the Department of Defense, the Federal Energy Regulatory Commission, and the Environmental Protection Agency and related or similar federally regulated projects). Other actions of concern include dredging and filling, and bank stabilization activities authorized or conducted by the USACE, and approval of water quality standards and pesticide labeling and use restrictions administered by the EPA.

Private or non-Federal entities may also be affected by these critical habitat designations if the activity requires a Federal permit, receives Federal funding, or the entity is involved in or receives benefits from a Federal project. For example, private entities may need Federal permits to build or repair a bulkhead, or install an artificial reef. These activities will need to be evaluated with respect to their potential to destroy or adversely modify critical habitat for yelloweye rockfish, canary rockfish, or bocaccio of the Puget Sound/Georgia Basin.

Questions regarding whether specific activities will constitute destruction or adverse modification of critical habitat should be directed to NMFS (see

ADDRESSES and FOR FURTHER INFORMATION CONTACT).

Information Quality Act and Peer Review

The data and analyses supporting this action have undergone a pre-dissemination review and have been determined to comply with applicable information quality guidelines implementing the Information Quality Act (IQA) (Section 515 of Public Law 106–554). In December 2004, OMB issued a Final Information Quality Bulletin for Peer Review pursuant to the IQA. The Bulletin was published in the **Federal Register** on January 14, 2005 (70 FR 2664). The Bulletin established minimum peer review standards, a transparent process for public disclosure of peer review planning, and opportunities for public participation with regard to certain types of information disseminated by the Federal Government. The peer review requirements of the OMB Bulletin apply to influential or highly influential scientific information disseminated on or after June 16, 2005. Two documents supporting these critical habitat proposals are considered influential scientific information and subject to peer review. These documents are the Biological Report (NMFS, 2014a) and the Economic Analysis (NMFS, 2014b). We distributed the draft Biological Report for peer review and addressed comments in the proposed critical habitat rule. We distributed the draft Economic Analysis for peer review, however, we did not receive any peer review comments. The peer review report for the draft Biological Report is available on our Web site at <http://www.wcr.noaa.gov>, or upon request (see **ADDRESSES**).

Classification

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996), whenever an agency publishes a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis describing the effects of the rule on small entities (i.e., small businesses, small organizations, and small government jurisdictions). We have prepared a final regulatory flexibility analysis, which is part of the final Economic Analysis (NMFS, 2014b). This document is available upon request (see **ADDRESSES**), via our Web site at <http://wcr.noaa.gov>. The

results of the regulatory flexibility analysis are summarized below.

The impacts to small businesses were assessed for the following broad categories of activities: utilities, nearshore work, transportation, water quality and other activities. Small entities were defined by the Small Business Administration size standards for each activity type, which were updated for Finfish fishing, shellfish fishing, and Other Marine Fishing (78 FR 37398; June 20, 2013). Taking this change as well as public comment into consideration, we have identified no additional significant alternatives that accomplish statutory objectives and minimize any significant economic impacts of the final rule on small entities. We do not forecast any costs to small entities related to utilities projects because the only consultation associated with utilities are pre-consultation/technical assistance and programmatic consultations, which do not include any cost to third parties; therefore, we do not expect any impacts to small entities related to utilities.

We estimated the annualized costs associated with ESA section 7 consultations incurred per small business under a scenario intended to provide a measure of uncertainty regarding the number of small entities that may be affected by the designations for each project category (NMFS, 2014c). It is uncertain whether small entities will be project proponents for these types of consultations, so the analysis conservatively assumes that all consultations will be undertaken by small entities, and that all such consultation will be formal. Under these assumptions, the costs to entities engaged in nearshore work are an estimated \$27,000 annually, or \$1,900 per entity. This cost represents less than 0.1 percent of annual revenues in this sector. The costs to entities engaged in transportation projects are an estimated \$46,000 annually, or \$7,700 for entities in this sector. This cost represents 0.29 percent of annual revenues. The costs to entities engaged in water quality projects are an estimated \$23,000 annually, or \$9,100 per entity. This cost represents 1.3 percent of annual revenues for entities in this sector. The costs for other entities, including fishing, would be approximately \$18,000 annually, or \$2,600 per entity. This cost represents 1.1 percent of annual revenues for entities in this sector.

In accordance with the requirements of the Regulatory Flexibility Act (as amended by the Small Business Regulatory Enforcement Fairness Act of 1996) this analysis considered various

alternatives to the critical habitat designations for these DPSs. These alternatives are described in the preamble above, and in the full Economic Analysis (see **ADDRESSES**). The alternative of not designating critical habitat for these DPSs was considered and rejected because such an approach does not meet the legal requirements of the ESA.

Executive Order 12866

At the guidance of OMB and in compliance with Executive Order 12866, "Regulatory Planning and Review," Federal agencies measure changes in economic efficiency in order to understand how society, as a whole, will be affected by a regulatory action. Our analysis of economic impacts can be found in NMFS (2014b), and this rule has been determined to be not significant under Executive Order 12866.

Executive Order 13211

On May 18, 2001, the President issued an executive order on regulations that significantly affect energy supply, distribution, and use. Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking any action that promulgates or is expected to lead to the promulgation of a final rule or regulation that (1) is a significant regulatory action under Executive Order 12866 and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy.

We have considered the potential impacts of this action on the supply, distribution, or use of energy and find the designation of critical habitat will not have impacts that exceed the thresholds identified above (NMFS, 2014b).

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act, NMFS makes the following findings:

(a) This final rule will not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute or regulation that would impose an enforceable duty upon state, local, tribal governments, or the private sector and includes both "Federal intergovernmental mandates" and "Federal private sector mandates." These terms are defined in 2 U.S.C. 658(5)–(7). "Federal intergovernmental mandate" includes a regulation that "would impose an enforceable duty upon State, local, or tribal governments" with two exceptions. It excludes "a condition of Federal assistance." It also

excludes "a duty arising from participation in a voluntary Federal program," unless the regulation "relates to a then-existing Federal program under which \$500,000,000 or more is provided annually to state, local, and tribal governments under entitlement authority," if the provision would "increase the stringency of conditions of assistance" or "place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding" and the state, local, or tribal governments "lack authority" to adjust accordingly. (At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement.)

"Federal private sector mandate" includes a regulation that "would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance; or (ii) a duty arising from participation in a voluntary Federal program." The designation of critical habitat does not impose a legally binding duty on non-Federal government entities or private parties. Under the ESA, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. While non-Federal entities which receive Federal funding, assistance, permits or otherwise require approval or authorization from a Federal agency for an action may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply; nor would critical habitat shift the costs of the large entitlement programs listed above to state governments.

(b) Due to the existing protection afforded to the designated critical habitat from existing critical habitat for salmon (70 FR 52630; September 2, 2005), Southern DPS of green sturgeon (74 FR 52300; October 9, 2009), bull trout (70 FR 56212; September 26, 2005), and the southern resident killer whale (71 FR 69054; November 29, 2006), we do not anticipate that this rule will significantly or uniquely affect

small governments. As such, a Small Government Agency Plan is not required.

Takings

Under Executive Order 12630, Federal agencies must consider the effects of their actions on constitutionally protected private property rights and avoid unnecessary takings of property. A taking of property includes actions that result in physical invasion or occupancy of private property, and regulations imposed on private property that substantially affect its value or use. In accordance with Executive Order 12630, this final rule does not have significant takings implications. A takings implication assessment is not required. The designation of critical habitat affects only Federal agency actions. We do not expect the critical habitat designations will impose additional burdens on land use or affect property values. Additionally, the critical habitat designations do not preclude the development of Conservation Plans and issuance of incidental take permits for non-Federal actions. Owners of areas included within the critical habitat designations would continue to have the opportunity to use their property in ways consistent with the survival of listed rockfishes.

Federalism

In accordance with Executive Order 13132, we determined that this final rule does not have significant Federalism effects and that a Federalism assessment is not required. In keeping with Department of Commerce policies, we request information from, and will continue to coordinate with, appropriate state resource agencies in Washington regarding this critical habitat designation. The designations may have some benefit to state and local resource agencies in that the areas essential to the conservation of the species are more clearly defined, and the essential features of the habitat necessary for the survival of the subject DPSs are specifically identified. It may also assist local governments in long-range planning (rather than waiting for case-by-case ESA section 7 consultations to occur).

Government-to-Government Relationship With Tribes

Pursuant to Executive Order 13175 and Secretarial Order 3206, we contacted the affected Indian Tribes when considering the designation of critical habitat in an area that may impact tribal trust resources, tribally owned fee lands or the exercise of tribal rights. The responding tribes expressed

concern about the intrusion into tribal sovereignty that critical habitat designation represents. These concerns are consistent with previous responses from tribes when we developed critical habitat designations for salmon and steelhead in 2005 (70 FR 52630; September 2, 2005). The Secretarial Order defines Indian lands as “any lands title to which is either: (1) Held in trust by the United States for the benefit of any Indian tribe or (2) held by an Indian Tribe or individual subject to restrictions by the United States against alienation.” Our conversations with the tribes indicate that they view the designation of Indian lands as an unwanted intrusion into tribal self-governance, compromising the government-to-government relationship that is essential to achieving our mutual goal of conserving listed rockfishes.

For the general reasons described in the Impacts to Tribal Sovereignty and Self-Governance section above, the ESA Section 4(b)(2) analysis has led us to exclude of all Indian lands in our critical habitat designations for yelloweye rockfish, canary rockfish, and bocaccio.

Civil Justice Reform

The Department of Commerce has determined that this final rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of Executive Order 12988. We are designating critical habitat in accordance with the provisions of the ESA. This rule uses standard property descriptions and identifies the essential features within the designated areas to assist the public in understanding the habitat needs of yelloweye rockfish, canary rockfish, and bocaccio of the Puget Sound/Georgia Basin.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This final rule does not contain new or revised information collection requirements for which OMB approval is required under the Paperwork Reduction Act (PRA). This rule will not impose recordkeeping or reporting requirements on state or local governments, individuals, businesses, or

organizations. Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

National Environmental Policy Act of 1969 (NEPA)

We have determined that an environmental analysis as provided for under NEPA is not required for critical habitat designations made pursuant to the ESA. See *Douglas County v. Babbitt*, 48 F.3d 1495 (9th Cir. 1995), cert. denied, 116 S. Ct. 698 (1996).

Coastal Zone Management Act (CZMA)

Under section 307(c)(1)(A) of the CZMA (16 U.S.C. 1456(c)(1)(A)) and its implementing regulations, each Federal activity within or outside the coastal zone that has reasonably foreseeable effects on any land or water use or natural resource of the coastal zone shall be carried out in a manner which is consistent to the maximum extent practicable with the enforceable policies of approved State coastal management programs. We have determined that any coastal effects of this proposed designation of critical habitat on Washington State coastal uses and resources are not reasonably foreseeable at this time. This proposed designation does not restrict any coastal uses, affect land ownership, or establish a refuge or other conservation area; rather the designation only affects the ESA section 7 consultation process. Through the consultation process, we will receive information on proposed Federal actions and their effects on listed rockfishes and the designated critical habitat upon which we base our consultation. It will then be up to the Federal action agencies to decide how to comply with the ESA in light of our opinion, as well as to ensure that their actions comply with the CZMA’s Federal consistency requirement. At this time, we do not anticipate that this designation is likely to result in any additional management measures by

other Federal agencies. We have determined that this proposed designation of critical habitat is consistent to the maximum extent practicable with the enforceable policies of the approved coastal management programs of Washington State. The determination has been submitted to the responsible agencies in the aforementioned states for review.

References Cited

A complete list of all references cited in this rulemaking can be found on our Web site at <http://www.wcr.noaa.gov/> and is available upon request from the NMFS office in Seattle, Washington (see ADDRESSES).

List of Subjects in 50 CFR Part 226

Endangered and threatened species.

Dated: November 3, 2014.

Samuel D. Rauch, III,
Deputy Assistant Administrator for
Regulatory Programs, National Marine
Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 226 is amended to read as follows:

PART 226—DESIGNATED CRITICAL HABITAT

- 1. The authority citation for part 226 continues to read as follows:
Authority: 16 U.S.C. 1533.

- 2. Add § 226.224 to read as follows;

§ 226.224 Critical habitat for the Puget Sound/Georgia Basin DPS of yelloweye rockfish (*Sebastes ruberrimus*), canary rockfish (*S. pinniger*), and bocaccio (*S. paucispinus*).

Critical habitat is designated in the following states and counties for the following DPSs as depicted in the maps below and described in paragraphs (a) through (d) of this section. The maps can be viewed or obtained with greater resolution (<http://www.wcr.noaa.gov/>) to enable a more precise inspection of critical habitat for yelloweye rockfish, canary rockfish and bocaccio.

(a) Critical habitat is designated for the following DPSs in the following state and counties:

DPS	State-counties
Yelloweye rockfish	Wa—San Juan, Whatcom, Skagit, Island, Clallam, Jefferson Snohomish, King, Pierce, Kitsap, Thurston, Mason.
Canary rockfish	Wa—San Juan, Whatcom, Skagit, Island, Clallam, Jefferson Snohomish, King, Pierce, Kitsap, Thurston, Mason.
Bocaccio	Wa—San Juan, Whatcom, Skagit, Island, Clallam, Jefferson Snohomish, King, Pierce, Kitsap, Thurston, Mason.

(b) Critical habitat boundaries. In delineating nearshore (shallower than 30 m (98 ft)) areas in Puget Sound, we

define critical habitat for canary rockfish and bocaccio, as depicted in the maps below, as occurring from the

shoreline from extreme high water out to a depth no greater than 30 m (98 ft) relative to mean lower low water.

Deepwater critical habitat for yelloweye rockfish, canary rockfish and bocaccio occurs in some areas, as depicted in the maps below, from depths greater than 30 m (98 ft). The critical habitat designation includes the marine waters above (the entire water column) the nearshore and deepwater areas depicted in the maps below.

(c)(1) *Essential features for juvenile canary rockfish and bocaccio.* Juvenile settlement habitats located in the nearshore with substrates such as sand, rock and/or cobble compositions that also support kelp are essential for conservation because these features enable forage opportunities and refuge from predators and enable behavioral and physiological changes needed for juveniles to occupy deeper adult habitats. Several attributes of these sites determine the quality of the area and are useful in considering the conservation value of the associated feature and in determining whether the feature may require special management considerations or protection. These

features also are relevant to evaluating the effects of an action in an ESA section 7 consultation if the specific area containing the site is designated as critical habitat. These attributes include:

(i) Quantity, quality, and availability of prey species to support individual growth, survival, reproduction, and feeding opportunities; and
(ii) Water quality and sufficient levels of dissolved oxygen to support growth, survival, reproduction, and feeding opportunities.

(2) Nearshore areas are contiguous with the shoreline from the line of extreme high water out to a depth no greater than 30 meters (98 ft) relative to mean lower low water.

(d) *Essential features for adult canary rockfish and bocaccio, and adult and juvenile yelloweye rockfish.* Benthic habitats and sites deeper than 30 m (98 ft) that possess or are adjacent to areas of complex bathymetry consisting of rock and or highly rugose habitat are essential to conservation because these features support growth, survival, reproduction, and feeding opportunities

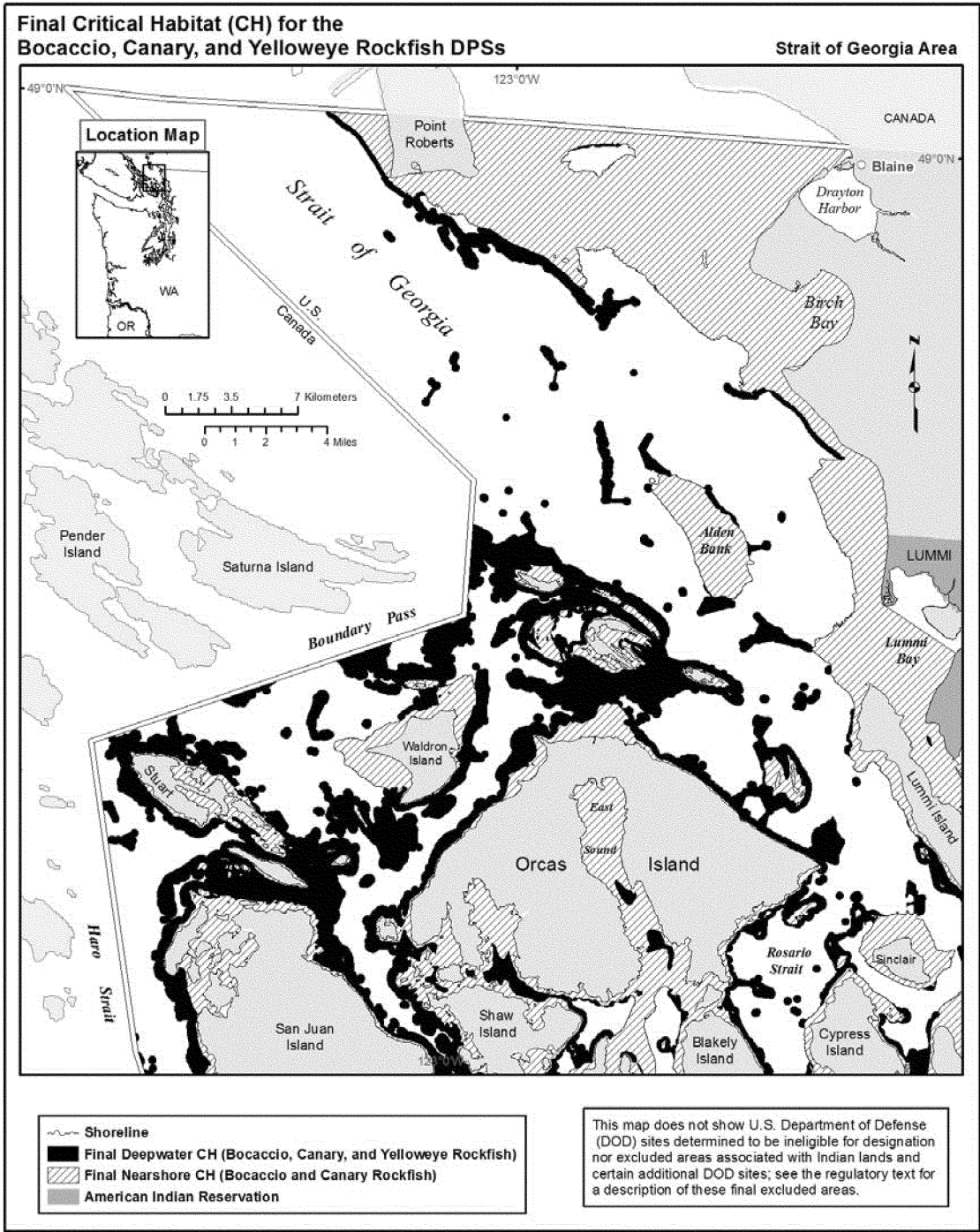
by providing the structure for rockfish to avoid predation, seek food and persist for decades. Several attributes of these sites determine the quality of the habitat and are useful in considering the conservation value of the associated feature, and whether the feature may require special management considerations or protection. These attributes are also relevant in the evaluation of the effects of a proposed action in an ESA section 7 consultation if the specific area containing the site is designated as critical habitat. These attributes include:

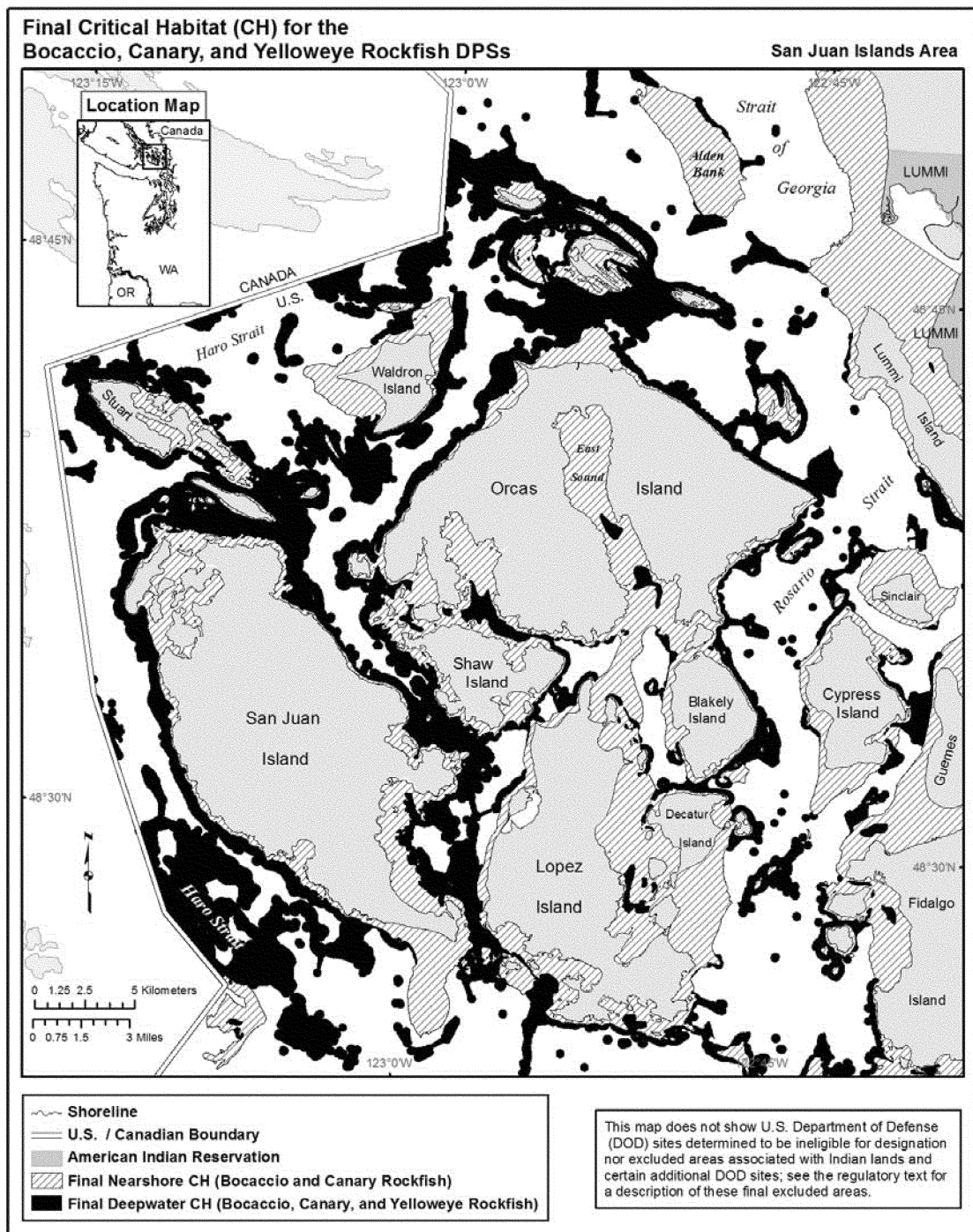
(1) Quantity, quality, and availability of prey species to support individual growth, survival, reproduction, and feeding opportunities;

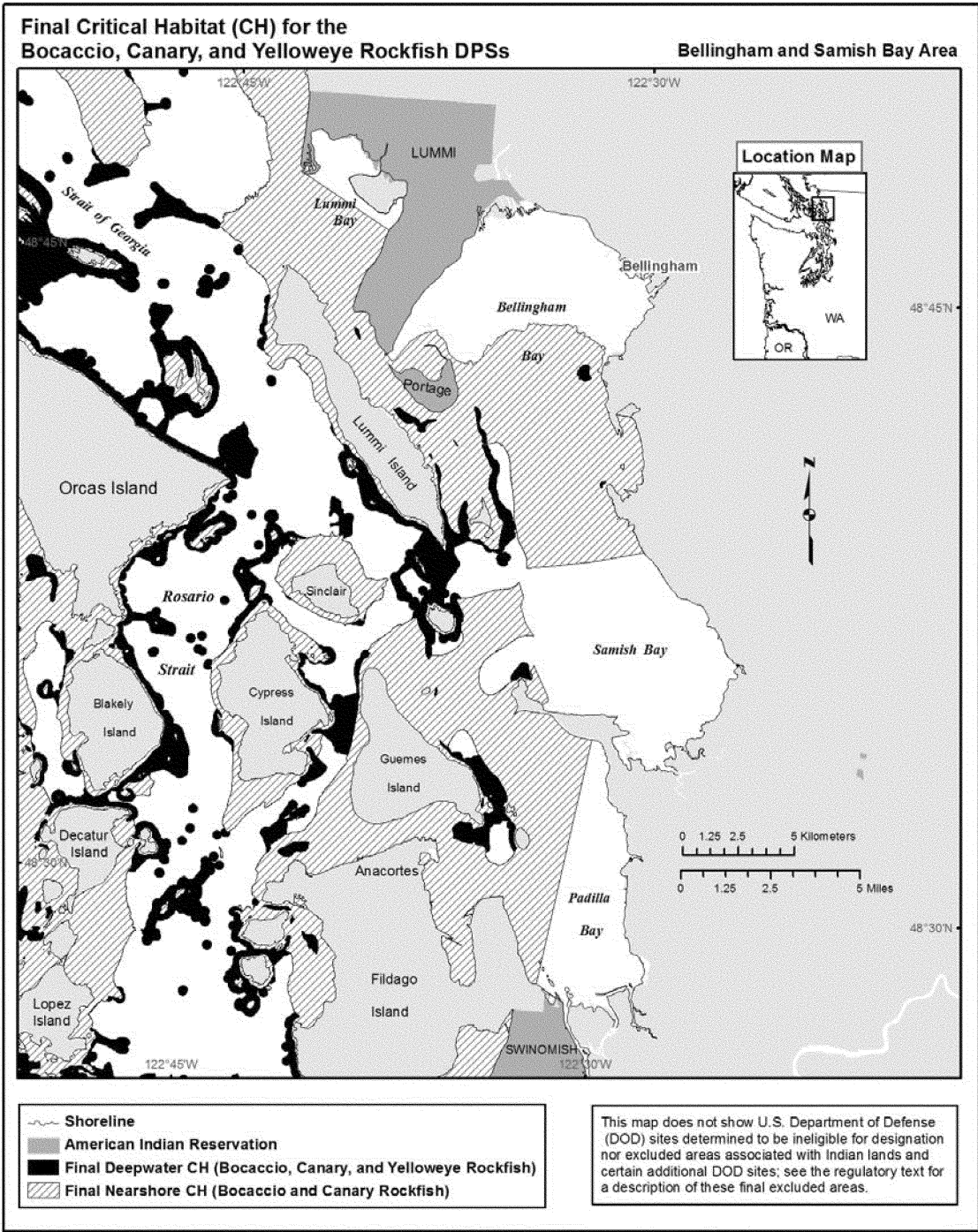
(2) Water quality and sufficient levels of dissolved oxygen to support growth, survival, reproduction, and feeding opportunities; and

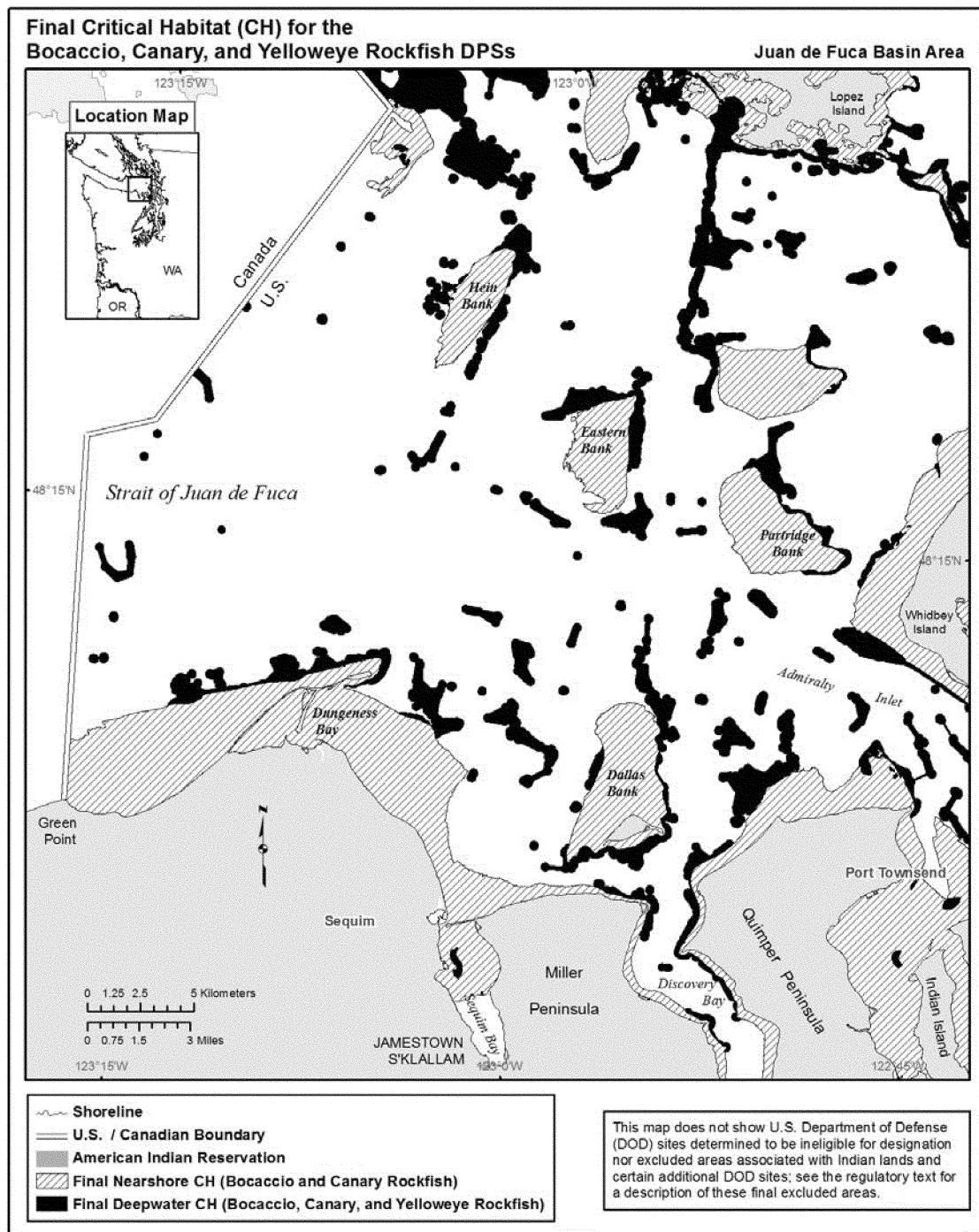
(3) The type and amount of structure and rugosity that supports feeding opportunities and predator avoidance.

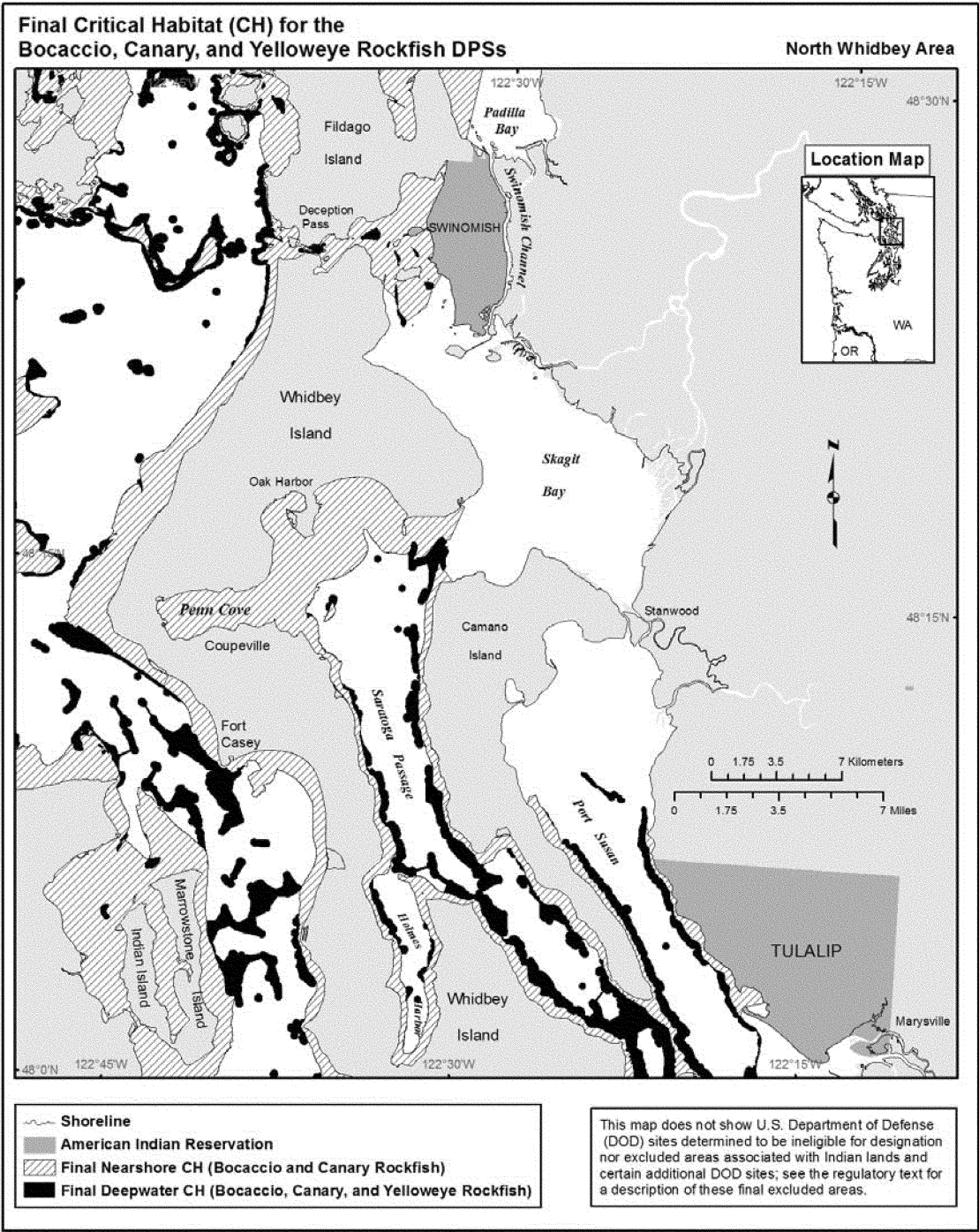
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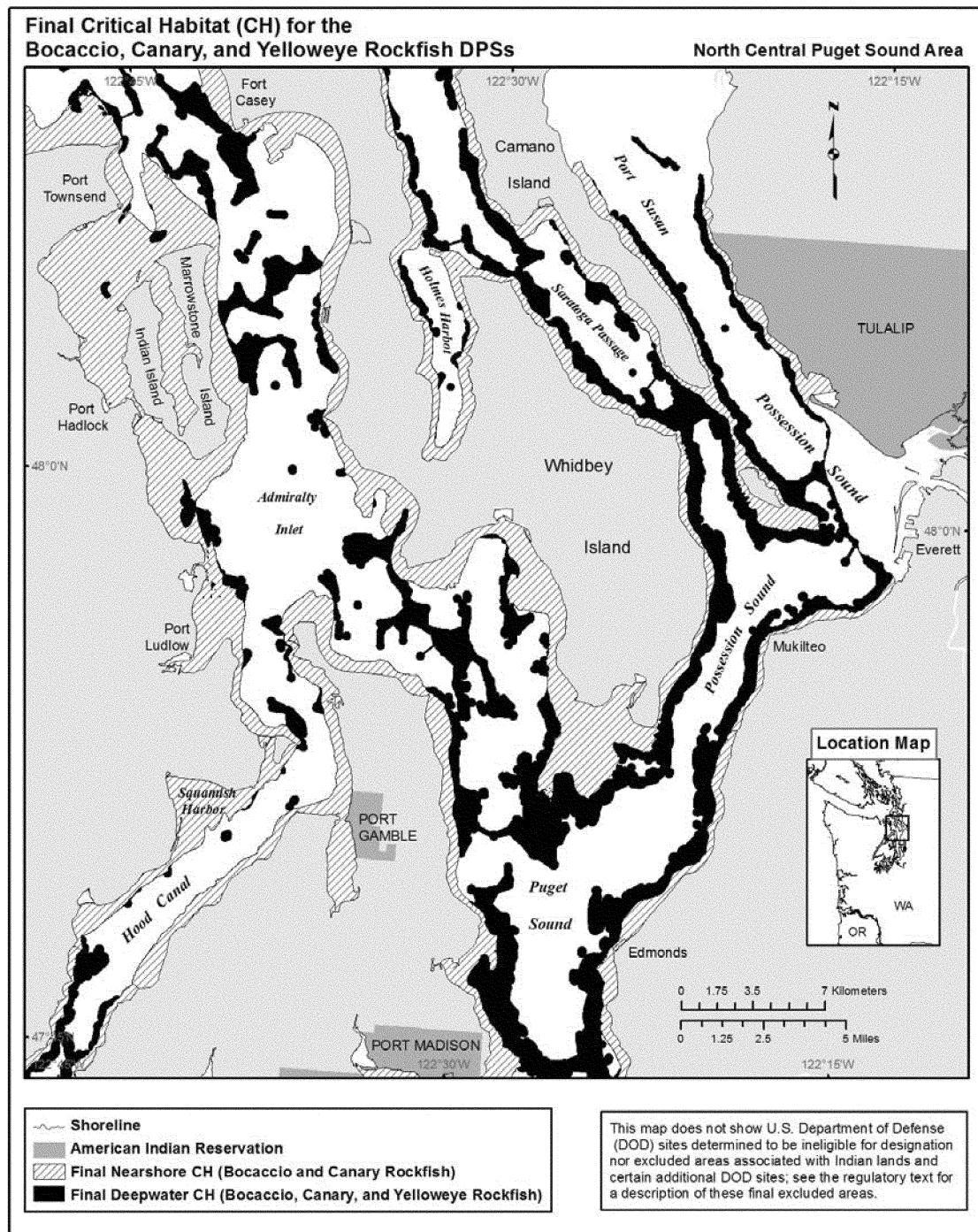


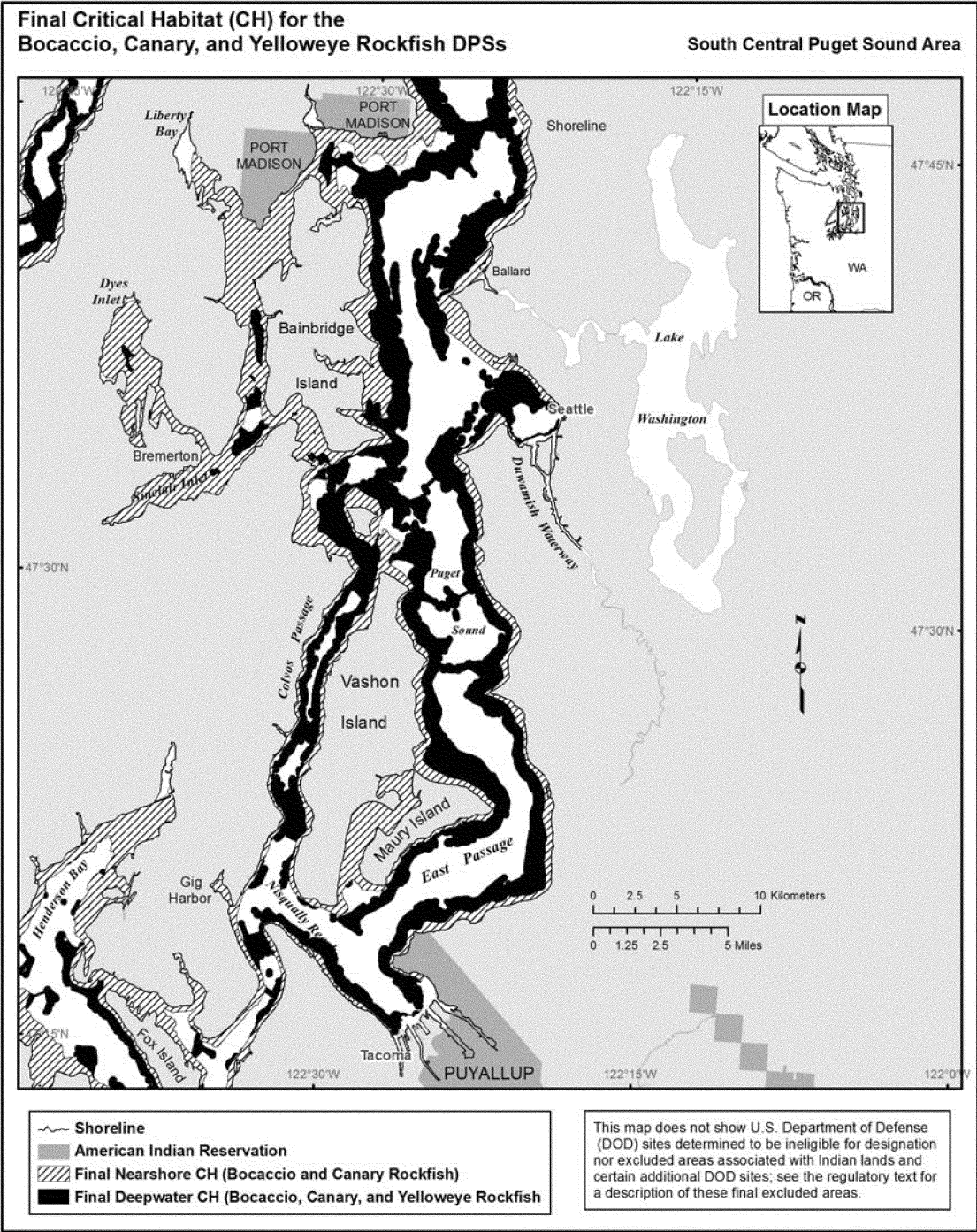


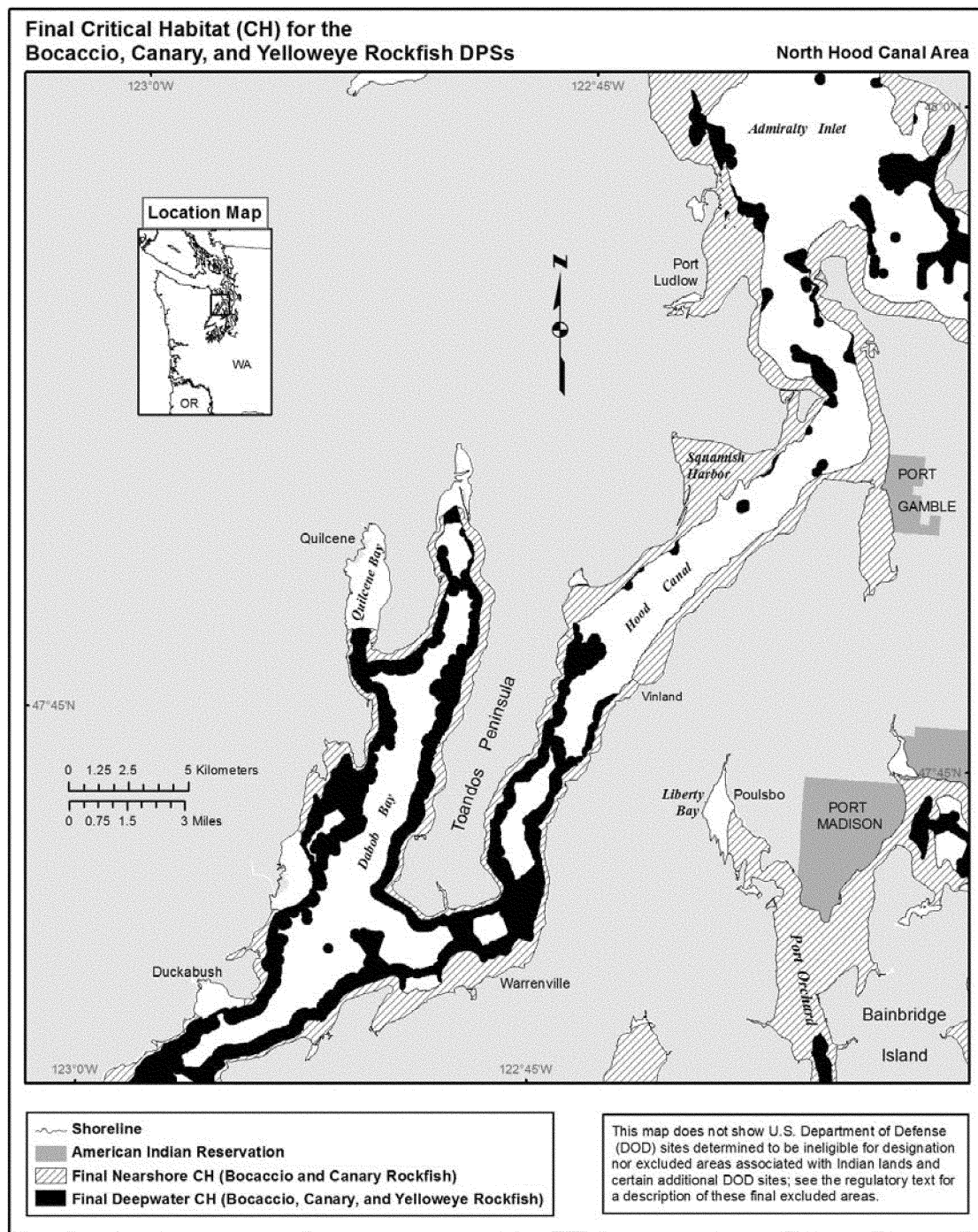


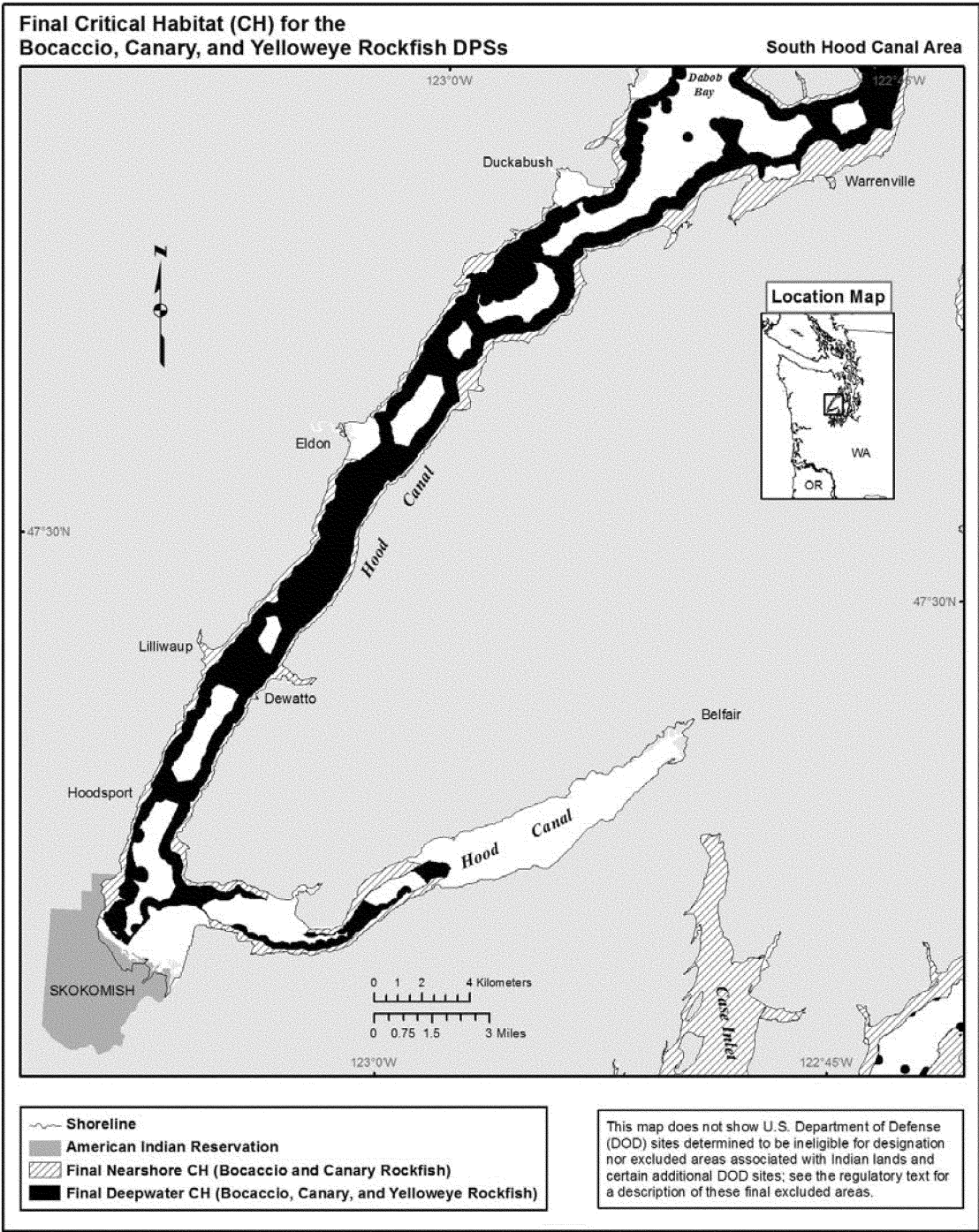


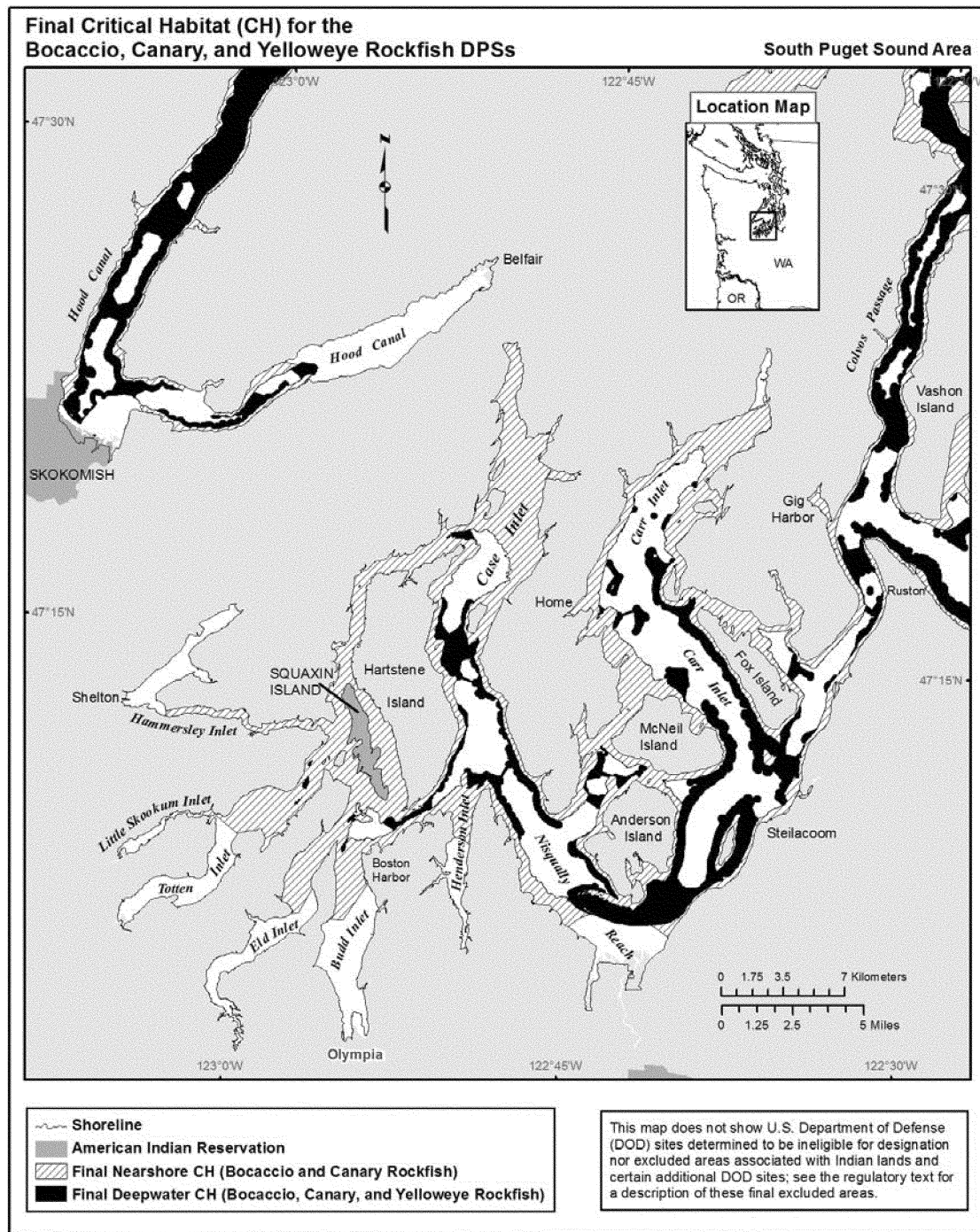












[FR Doc. 2014-26558 Filed 11-12-14; 8:45 am]

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FEDERAL REGISTER

Vol. 79

Thursday,

No. 219

November 13, 2014

Part V

The President

Notice of November 12, 2014—Continuation of the National Emergency
With Respect to Iran

Presidential Documents

Title 3—

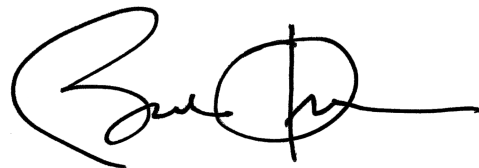
Notice of November 12, 2014

The President

Continuation of the National Emergency With Respect to Iran

On November 14, 1979, by Executive Order 12170, the President declared a national emergency with respect to Iran and, pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706), took related steps to deal with the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States constituted by the situation in Iran. Because our relations with Iran have not yet returned to normal, and the process of implementing the agreements with Iran, dated January 19, 1981, is still under way, the national emergency declared on November 14, 1979, must continue in effect beyond November 14, 2014. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency with respect to Iran declared in Executive Order 12170.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
November 12, 2014.

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